

# **Utilising Open Source Software Development for Effective EHR Development**

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Developing national Electronic Health Record (EHR) systems has been a challenge for many countries. The costs in various cases have considerably increased and the projects are behind schedule without matching the aims. Moreover the users have not been very satisfied with those systems because of the problems that have appeared in the current developments. These have been attributed to the lack of attention on the social aspects of developing and adopting EHR systems.

Free/Libre/Open source software development on the other hand, is a software development process which has many social elements and follows a different approach to the evolution of systems than the one found in “traditional” processes.

After presenting an overview of open source software development and issues related to EHR systems this work supports the use of an open source software development process at the heart of EHR development efforts in order to enable a radically different approach. This process places emphasis on collaboration, on the development of systems that are shared between the collaborating organisations, in encouraging the involvement of academia and volunteers to these projects, all of which could result in reduced development costs and in making the process more effective.

Key words and terms: Electronic Health Records, Open Source Software, Health Information Systems, Software Quality, Software Process Improvement

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# 1 Introduction – The Research Problem

Healthcare systems are facing multiple problems worldwide, such as increasing costs [Charette, 2006] [Noteboom and Qureshi, 2011], poor quality of service and lack of patient care integration [Noteboom and Qureshi, 2011], with the industrial countries spending on average 10% of their Gross Domestic Product on healthcare [Charette, 2006]. The increased need to manage chronic illnesses, along with an ageing population, impose an even greater burden on healthcare systems [Spil et al, 2010].

Several countries have invested in Health Information Technology (HIT) initiatives, aiming at reducing medical errors, increasing quality of care and patient mobility, all of which could result in reduced healthcare costs. Some of these countries are Australia, Canada, the US and many EU countries [Charette, 2006] [European Commission, 2007] [Jalal-Karim and Balachandran, 2008]. The national Infostructure project in Canada, had received a total of 1.2B Canadian dollars in 2004 to advance Electronic Health Records (EHR) and tele-health systems [Noseworthy, 2004], while the Obama administration in the US, has spent \$19B in stimulus support for EHR systems with the aim of reducing the estimated, 98,000 deaths and millions of injuries of injuries due to medical errors [Shneiderman, 2011], both of which demonstrate the amount of attention given towards HIT.

At the centre of these initiatives are the EHR systems [Charette, 2006] [Jalal-Karim and Balachandran, 2008] [Karim et al, 2011]. Although we will look at the meaning of EHR in more detail later, it is enough to say at this point that an EHR is a repository of patient data, stored and exchanged securely in digital form, which is accessible by multiple authorized users [Häyrinen et al, 2008]. An EHR related project is present in the HIT strategic plan of most EU countries [European Commission, 2007] and national EHR implementations are internationally pursued [Cresswell et al, 2012]. The EHR systems are expected to increase efficiency of healthcare delivery, improve patient information collection, speed up administrative processes, improve working conditions and, with a high enough level of user acceptance, result in improved safety, efficiency and quality in healthcare [Carayon et al, 2009].

However, several attempts at implementing a national EHR have faced problems. The rising implementation costs are an important issue, as in Australia where they started from an estimated AU\$500M in 2000 and rose to AU2\$B in 2006 [Charette, 2006], in the U.K. they started from an estimated £2.6B in 2002 to at least £15B in 2006 [Charette, 2006], and in the U.S. the estimate was \$100B to \$150B in implementation costs and \$50B per year of operation [Charette, 2006]. There is a conflicting view on EHR functionality, information profile and implementation strategy [Charette, 2006] and the failures are attributed to lack of attention at the socio-economic factors [Charette, 2006], and to approaching the issue of implementation as a technical one while neglecting the human and organisational aspects [Carayon et al, 2009]. After presenting the research problems to be handled, I next formulate the research questions.

## 1.1 Research Questions and Motivation

The reason for starting this research exploration was a personal interest on the dynamics of open source software (OSS) development process and its quality assurance issues. There is a great variety in OSS development, and the community elements along with the interactions that take place inside the community can make OSS a very flexible tool for developing systems in an evolutionary fashion with the possibility of a substantial user input. The main aim has been to argue about the possible use of OSS beyond simply using existing free software components of OSS projects.

This particular argument can be made in the case of EHR systems if three research questions are answered. These questions were considered to be :

1. How is OSS developed and what is the form of this development process?
2. How are EHR systems developed and implemented at this point and what problems are associated with this process?

Based on the answers provided in questions one and two above, I will proceed to answer the third research question :

3. Why an OSS process could (or could not) be beneficial for the development of EHR systems.

The ambition of this work is to show how different social structures in the real-world can be fostered through the use of an OSS development community resulting in better systems and allowing the evolution of both the community of the users and the systems themselves. The perceived success, from my point of view, would be to stimulate some discussion on the possibility to use OSS in a way like this in large scale projects with an evolutionary nature, where the community of users has to mature along with the systems.

## **1.2 Research Process And Methods**

The research process that was followed for this work was an incremental process of literature analysis. In each iteration a literature analysis took place which was aimed at enriching previous knowledge according to research questions one and two. During every iteration the basic criteria to answering the questions one and two were :

- Does this give enough information on the implementation aspects of EHR systems, so that an OSS process can be seen as an alternative?
- Or, does this rule out the possibility of using an OSS process to improve the current approach?

The first iteration dealt with a simple question. It was necessary find out first and answer if the software qualities that are necessary for EHR systems can be satisfied from an OSS process. The next iterations aimed at attaining a more holistic view of EHR implementation and adoption, focusing more on social aspects. During the third iteration the use of OSS in this problem was considered and in the fourth iteration the possibilities that were seen based on the information gathered from the literature analysis were outlined. The literature analysis was considered adequate for answering these two questions.

What	Why	How
OSS development process outline	Necessary in order to understand what the possibilities that this process offers	Iterative literature analysis on multiple aspects of OSS
EHR problems related to the development and implementation process	Recognise where the introduction of a different process would have an impact	Iterative literature analysis on problems of EHR implementation until enough information indicating or ruling out the possibility of applying an OSS development process for EHR development
Explore if an OSS process can (or cannot) be beneficial for EHR development	Why the findings of the questions one and two can or cannot be combined to solve existing problems	Argumentative approach based on the answers to the previous questions

*Table 1: Research Questions - Reasons for their choice and the method they were approached*

### 1.3 Thesis Outline, Who Can Use This Thesis And For What?

The thesis starts by presenting an overview of OSS development. This chapter is considered as an answer for research question one. It presents issues such as :

- Software quality in OSS
- Reasons stakeholders get involved in OSS
- How the process unfolds
- The structure of the communities in OSS
- How OSS has evolved over time
- A framework for rating how “open” is a project based on four dimensions.

An overview of EHR systems follows. This chapter is considered the answer to research question two. The overview includes information :

- On the term EHR
- Reasons for using EHR systems
- Practices in different countries regarding national EHR systems and their strategies
- Information on the systems currently used in healthcare organisations
- Issues regarding the value of EHR systems
- Implications for a strategic approach.

The outcome of the analysis is presented afterwards. This has the form of an argument regarding the positive dynamics and the challenges that a different approach having at its core the use of OSS might have. This part contains thoughts on the form this process might take, focusing on both external and internal aspects to the development process. This chapter tries to provide an adequate answer to research question number three.

The suggested approach could benefit most stakeholders of the EHR systems, and companies developing systems that operate on top of EHR systems or EHR modules. However, it would possibly be detrimental for the existing developers of EHR systems



who would have to adapt to a new landscape while seeing their systems getting devalued. The conclusion comments on the limitations of this work and possible future directions.

This work could be of value to policy makers who can consider this approach and the possible value such a policy can have for :

- local research
- lowered costs through the larger scale of implementation for many healthcare organisations by using a single core team and the contributions of volunteers
- developing high quality systems as a result of this process.

## 2 Open Source Software Development

### 2.1 Introduction

This chapter is an overview of OSS development. OSS is technically, a software licensing model. However the impact it has had on software development practices has been significant [Capra and Wasserman, 2008].

A software product can be considered free and open source (FOSS) if its license grants the right to use the software, copy and redistribute it, modify it and distribute the modified version [Samoladas and Stamelos, 2003].

Those four characteristics cannot give a complete picture on OSS. OSS is not homogeneous, and despite many types of software sharing this label there are differences in practices, culture and licenses [Kilamo et al, 2011]. In the case of licenses for example, some are permissive, some impose restrictions on redistribution and others impose the use of the same license on any derivative work [Kilamo et al, 2011]. What all OSS projects have in common are *transparency* of development and the ability to construct complex systems out of readily available software parts [Kilamo et al, 2011].

A description that is used quite often in literature to describe the life-cycle of an OSS project supports that a person or a group have an idea of how to write a software to satisfy some personal need, they develop some software to satisfy it and make it available online with its source code. Since the software and the source code are available, people make contributions in the form of bug fixing or added functionality. The contributions form the new test version of the software which after adequate testing and corrections becomes the next stable version of the software, and the development cycle starts again with new contributions. [Samoladas and Stamelos, 2003]

These interactions take place in the context of a community of users and developers and the systems evolve according to the needs of the community. The software system is not necessarily carefully designed in advance. The access to the source code and the right to create derivative works allows the system to evolve, not only according to initial plans but “naturally” as well [Nakakoji et al, 2002].

This chapter contains :

- The presentation of a study on (Free and OSS) F/OSS quality
- An overview on the reasons for different stakeholders to use OSS or participate in the development process
- A structured description of the OSS development process
- A framework for assessing how “open” is the management of the project
- How communities evolve and finally how OSS development has taken a more business-friendly turn.

### 2.2 Open Source Software Quality

A study by Samoladas and Stamelos [Samoladas and Stamelos, 2003] gives us some information regarding software quality in OSS. The ISO 9126 quality model was used to assess the quality of FOSS according to information found in literature. The major properties of the ISO quality model are functionality, reliability, usability, maintainability, portability and efficiency [Samoladas and Stamelos, 2003] and information on the performance of OSS according to those properties is given.

Functionality refers to the existence of functions required to fulfil the users needs. Some OSS projects have eliminated all the competition in their application area, with BIND (Berkeley Internet Name Domain) being given as an example in the paper.

Moreover, There is a number applications that are very popular such as programming tools, relational databases and one very noteworthy example is the Apache web server which was used by 62.7% of the web servers at the time of the study. It is also suggested that since the OSS movement has shown a commitment to following implementation standards, access to those standards without royalty fees can produce feedback from users of those implementations which would lead to improvement and optimisation of the standards. On the negative side here is the lack of popular desktop applications or applications to address specific needs, putting into question the strength of OSS as an approach in developing applications for a specific group of users. [Samoladas and Stamelos, 2003]

Reliability refers to the ability of the system to maintain its performance for a period of time under specific conditions. An important aspect to reliability is finding and fixing bugs present in the software. One of the strengths of OSS is the very quick rate of bug fixing which in some cases has been quite rapid. In the case of Apache project for example, a cumulative 50% of the problems were fixed within one day, 75% with 42 days and 90% within 140 days. Moreover in two very mature projects, Mozilla and Apache, the process they use for their development leads to fewer bugs making it into the source code. Furthermore, the availability of the code is considered a positive aspect in the long term for improved software security. [Samoladas and Stamelos, 2003]

Usability refers to how much effort from the side of the user is necessary to use the system. Regarding this property OSS has not demonstrated anything better than what is found in proprietary software. This is attributed to the lack of designer skills among the developers, and the inherent differences between the role of the developer and the role of the user, as well as the lack of usability experts in the community. Moreover Samoladas and Stamelos note that usability is something that has to be planned in advance, something that is not always the case of OSS development. [Samoladas and Stamelos, 2003]

Regarding the rest of the attributes, namely maintainability, portability and efficiency, Samoladas and Stamelos mention the importance of maintainability for OSS development, which can be seen as an open maintenance process, how it is possible to port some software application when the source code is available and that no studies have been done on efficiency. [Samoladas and Stamelos, 2003]

In general OSS quality seems to be high, comparable to proprietary closed-source applications and in some cases it is higher than closed source software. This is a very good reason to consider OSS alternatives to closed source applications since OSS is free of charge. This also shows that the process itself seems to have some strengths attributed to the availability of the source code.

## **2.3 Stakeholders' Reasons For Getting Involved In Open Source**

OSS might be used by simple users, companies, public organizations and developers as well.

Reasons such as cost and software quality should be obvious based on what was presented. It is important though, to have a look at some reasons why businesses would want to release their software as OSS, why developers would want to participate in OSS development and why public institutions might be interested in using OSS.

Regarding the involvement of companies in OSS development, Sirkkala et al. have grouped the objectives that a company can achieve through OSS into the categories of marketing, business models, and shared costs [Sirkkala et al, 2009].

A company can satisfy a number of goals relevant to marketing such as the promotion of growth in the field, advertising itself and its products through participation in OSS communities and recruiting skilled members from the community

who have become familiar with the company and its product through their participation in the community. [Sirkkala et al, 2009]

The company can achieve a set of business goals by providing services based on the product for a fee, or offer consulting. In the case that the company uses the software for its internal processes the community can extend the software while lowering the costs for the company and possibly allowing them to be shared among the company and other users. Other benefits in this category are gaining knowledge about and networking with other companies and communities. The aspect of shared costs seems to be closely related to the business models. Software related issues here are adding functionality through the community and/or improving overall quality of the product. [Sirkkala et al, 2009]

Moving on to the developers, reasons to participate in this sort of development are learning by expert developers through contributions and interactions within the community [Nakakoji et al, 2002], possibly being recruited by companies which might make use of the community for recruiting, the feeling of creativity felt during development and peer recognition through the software development [Camara and Fonseca, 2007]. An increasing number of developers though, take part in OSS development as part of their job. In Europe the majority of OSS developers receives some reward for their work in OSS [Camara and Fonseca, 2007].

Finally, public institutions might benefit from lower cost and independence from proprietary software which would help avoid vendor lock-in [Camara and Fonseca, 2007]. Other potential benefits are availability of low-cost software and the ability to adapt the products to fit local needs [Camara and Fonseca, 2007]. One of the problems is that there are not many successful desktop applications available with most of the successful systems being infrastructural products and adapting the software is not always an easy task [Camara and Fonseca, 2007].

## **2.4 The Development Process Followed In Open Source Software Development**

As we have seen a number of different stakeholders can benefit by participating in OSS development, and that the OSS development communities have produced some products of a very high quality. What is important now is to have a structured picture of the general form of this development process. A structured approach of a general OSS development process is provided by Anthony Senyard and Martin Michlmayr in [Senyard and Michlmayr, 2004].

Senyard and Michlmayr follow the terminology of the metaphor of the cathedral and the bazaar which is found in OSS literature and was given by Eric Raymond, who compared traditional proprietary software development to building a cathedral and then the diametrically opposite of a market bazaar is compared to OSS development where software is built through the interactions of the community. Senyard and Michlmayr argue that these are phases that a software passes, within the same life-cycle and are not mutually exclusive states found in one or the other development process. [Senyard and Michlmayr, 2004]

### **2.4.1 The Cathedral Phase – Lifecycle Considerations**

The development of an OSS project starts by an individual or a small group, called the core group, which has not made any contact with a community. The development process at this phase is similar to the processes followed in proprietary software and contains the activities of requirements, design, implementation and testing which are not necessarily done in a well defined manner. The role of design should be emphasised here, as a modular design is necessary and can have a profound effect on the evolution of the community. [Senyard and Michlmayr, 2004]

When starting an OSS project it is first suggested to search for an existing project which aims to satisfy the same need as the project in mind or aiming at doing so according to its scope and vision. If a project of this sort is found, then the potential project initiator can participate in it. In case of disagreement with the design decisions, dislike towards the individuals developing it or the programming language used the potential initiator might decide as well not participate. Senyard and Michlmayr note that these reasons sometimes can be legitimate because of fundamental flaws in existing projects but they can lead to “two mediocre software projects while one superior software project would have been possible had the two efforts joined forces”. [Senyard and Michlmayr, 2004]

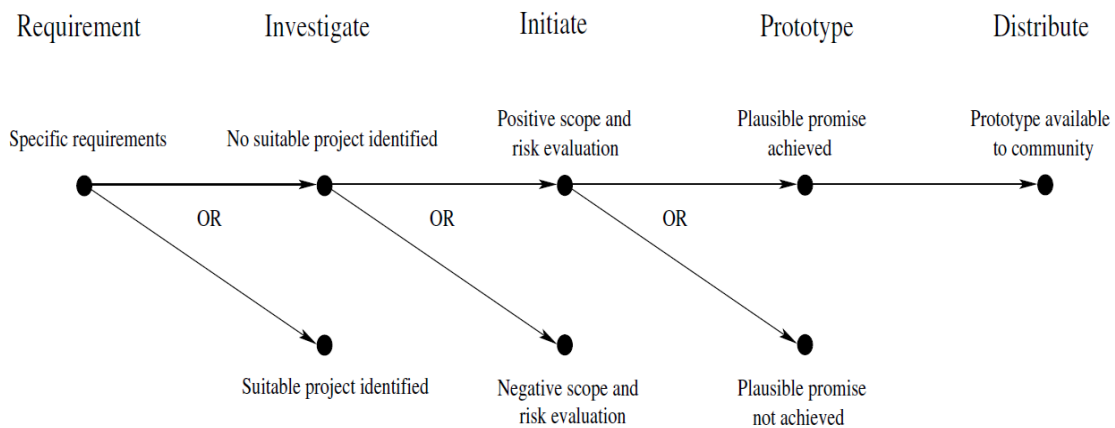


Figure 1: Detailed Cathedral Phase [Senyard and Michlmayr, 2004]

#### 2.4.2 The Transition – Methodological Considerations

The transition of the process from cathedral to the bazaar can start once a working prototype has been developed [Senyard and Michlmayr, 2004]. The transition has to begin at the right moment, when the prototype is stable, with a sufficient amount of functionality but at the same time in need of improvement [Capiluppi and Michlmayr, 2007]. Another point found from empirical research in two projects is the tendency of new developers to work on newly added modules, indicating that the transition has to be actively sought by the core members who should try to attract new contributors by adding new ideas to the project and expanding it in new directions [Capiluppi and Michlmayr, 2007].

Some other elements important during the transition are mentioned in the work of Kilamo et al [Kilamo et al, 2010] and while they deal more specifically with proprietary software released as OSS, some of those aspects seem interesting for all the cases of transition. Those elements are related to the software, the community, the legalities, and the releasing authority [Kilamo et al, 2010].

Software related issues revolve around the architecture which has to be extensible, the source code which must follow conventions, be approachable to others and documented. Software quality is tied to the architecture to some extent and also the perceived quality must be high to attract users. [Kilamo et al, 2010]

The type of the desired community and the role of participants dictates to a degree what will be released, this is relevant in the cases of releasing parts of a proprietary software as . The purpose of the software should be something that attracts users, fulfils their needs and sparks the interest of developers so that it can attract contributions. There has to be a potential for an active community to reap the benefits, as 100 users can support one full time developer, and the active community can take over activities such as guiding new users, creating documentation, and testing in order to allow

developers to fully focus on implementation. The last element in community issues is concerned with the partners of the developer entity. Either that is a company or a different type of group, the decision will directly affect them. [Kilamo et al, 2010]

Legalities include licensing and branding, which are things that all projects must deal with, and copyright and intellectual property rights which seem to be more specific to companies. The choice of the license will have an effect on the type of users the project will attract. Some licenses restrict commercial use of the software while others can be considered business-friendly and choosing the second for example has more chances of attracting businesses. Branding refers mostly to finding a good name available for the project. Finally, copyright and intellectual property rights are not an issue when the code is owned by the releasing authority but if the components are owned by other organisations or individuals they have to be clear before being released as OSS. [Kilamo et al, 2010]

The releasing authority is the last element that Kilamo et al address in their framework. It can be a company or another entity such as a university, a non-profit organisation or an individual. The transition requires a change of culture and mindset towards outside developers from the releasing authority by providing them with similar guidelines and conventions as the internal developers, providing equal access to the source code and showing mutual respect. Laying down a process for participants to follow, providing support and infrastructure for distributing the code, and enabling participation and communication within the project, are the responsibility of the releasing authority.[Kilamo et al, 2010]

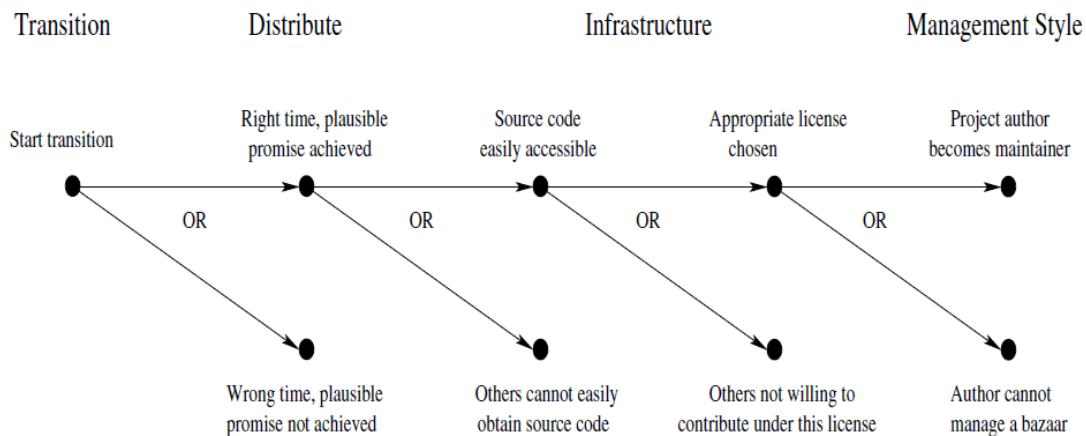


Figure 2: Detailed Transition [Senyard and Michlmayr, 2004]

### 2.4.3 The Bazaar Phase

A successful transition and the growth of a community will put the project in its bazaar phase. The aim of OSS projects is to reach this phase and gain access to a community of contributors [Senyard and Michlmayr, 2004]. Key characteristics of this phase are the cooperation within the community in order to review and modify the code and volunteers working on the project at the same time [Senyard and Michlmayr, 2004].

The code is publicly available and contributions are encouraged during this phase. Contributions come in the form of feature request, feature implementation, bug report and bug fixing, writing tutorials and user documentation and reporting usability problems. [Senyard and Michlmayr, 2004]

The advantages of the bazaar phase are *peer review*, *concurrent development*, and *opening the requirements to the users* [Senyard and Michlmayr, 2004]. The availability of the code enables the *participation* of a wide base of participants at different levels

and this creates the conditions for a better bug fixing environment, the concurrent development can allow activities like adding features and fixing bugs to happen at the same time [Senyard and Michlmayr, 2004]. In order for concurrent development to take place a high degree of modularity in the design of the software is required [Senyard and Michlmayr, 2004].

This process can sometimes lead to a *complete redesign* of the system [Senyard and Michlmayr, 2004]. The *expanding requirements* and the *parallel development* can make the initial design inadequate [Senyard and Michlmayr, 2004]. The bazaar phase generates insights into the design showing limitations, the design might not be flexible enough to incorporate the new features and the drive for technical excellence present in the community can be reasons that lead to this redesign [Senyard and Michlmayr, 2004]. This process is once again done following a cathedral style with a core team carrying it out [Senyard and Michlmayr, 2004]. Senyard and Michlmayr also support that since there are no constraining economic requirements this drive for excellence can be pursued [Senyard and Michlmayr, 2004], but if a company is the driving force of the project the economic requirements would definitely restrict this decision.

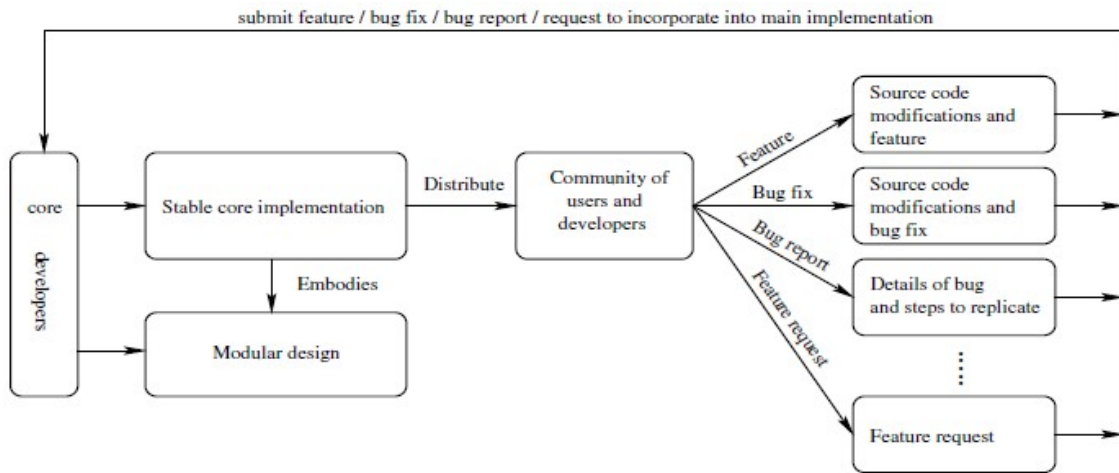


Figure 3: The Bazaar Development Life-cycle [Senyard and Michlmayr, 2004]

The bazaar phase is not reached by all the projects and not all of them have to reach it. Projects with a small scope can be written by only one person and still have a high quality, but projects with a larger scope can only be completed by a community [Capiluppi and Michlmayr, 2007]. Examples of this can be system utilities that implement a single simple function as opposed to the various distributions of Linux operating systems which are a collection of multiple utilities and other complex applications.

In the case of companies releasing their software as OSS, there has to be some effort in order to facilitate the growth of a community. A set of data can be used in order to be able to make decisions that support this goal [Kilamo et al, 2011]. The period when the community is fostered should be placed in the beginning of the bazaar phase.

This period has been called the community watchdog phase and focuses on the concentration and analysis of data [Kilamo et al, 2011]. Some of the important information that can be utilised are the number of contributors, the number of mailing list subscribers, the amount of requests, feedback, inquiries, the visibility of the project in social media, the number of participants in project events and meetings, the number of scientific publications mentioning the community, the number of downloads, and the number of reported bugs [Kilamo et al, 2011].

For the development activity of the project, the type and impact of contributions and the number of projects built on top of the product are interesting measures [Kilamo

et al, 2011]. These measures could be utilised by other organisations aiming at building a community around them and release software as OSS.

## 2.5 Community Structure And Evolution Of Open Source Projects

Nakakoji et al describe the structure of an OSS community through an onion layer model, with the most influential actors of the project being positioned to the inner layers being and the less influential to the outer ones. The most influential one is the project leader who has more influence than core members, who in turn have more influence than active members and so on [Nakakoji et al, 2002].

The participants in OSS projects can be :

1. Passive users : They simply use the product. [Nakakoji et al, 2002]
2. Reader : The active users of the system who try to understand how it works by reading the code. [Nakakoji et al, 2002]
3. Bug Reporter : The people who report bugs. They do not fix the bugs, neither it is necessary for them to read the code. [Nakakoji et al, 2002]
4. Bug Fixer : They fix bugs found by them or reported by bug reporters. They should understand the parts of the code where the bug is found. [Nakakoji et al, 2002]
5. Peripheral Developer : They contribute through adding new functionality to the project. Their involvement is short and sporadic. [Nakakoji et al, 2002]
6. Active Developers : Regular contributors of features and bug fixes. They are highly influential to the development of OSS. [Nakakoji et al, 2002]
7. Core Members : They guide and coordinate the project. The members have been involved in the project for a long period of time and have made significant contribution to the project. [Nakakoji et al, 2002]
8. Project Leader : This is usually the person who initiated the project. Is responsible for the vision and the overall direction of the project. [Nakakoji et al, 2002]

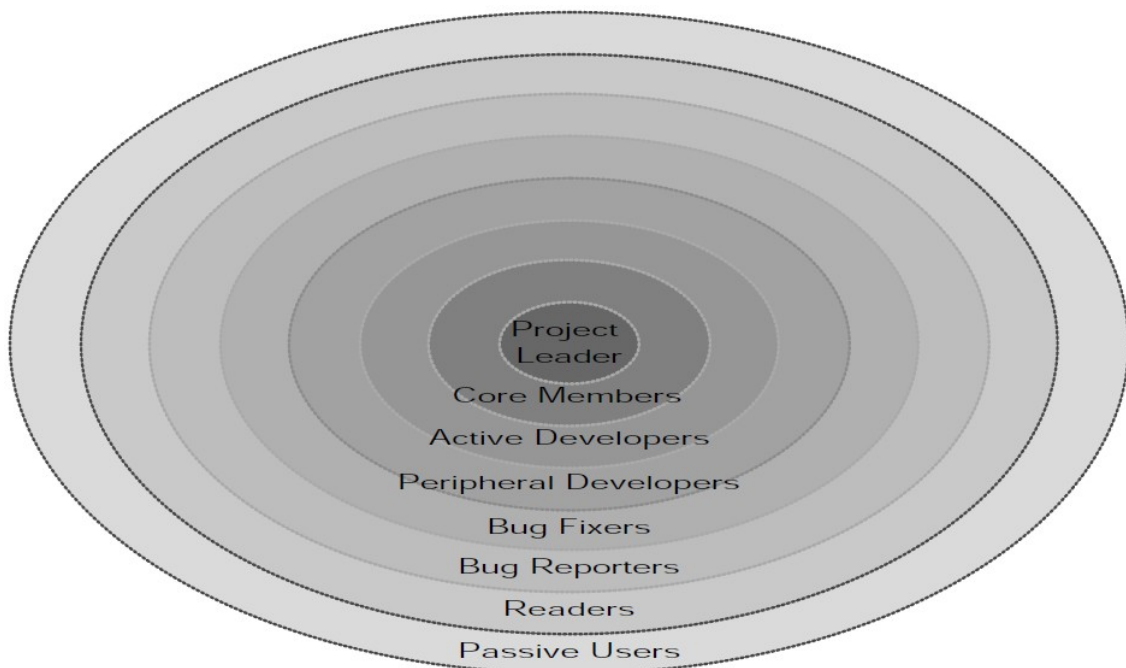


Figure 4: The General Structure of A Community [Nakakoji et al, 2002]



These roles do not exist in all the projects and the percentage of each varies from project to project. What is common though is that most of the members are passive users and most of the code is contributed by a small number of developers [Nakakoji et al, 2002]. Moreover, a user can assume different roles and may start as a passive user and through contributions can move to the inner layers of the model [Nakakoji et al, 2002]. In the community it is important to enable mobility and have members aspiring to be promoted into the inner layers, as this increases the sustainability of the system, because a replacement can be found if a core member decides to leave the project [Nakakoji et al, 2002]. However there has to be some caution in how open the project is or how much promotion is possible as “too much openness can be harmful when it leads to incompetent developers or people who demotivate important contributors getting involved”[Capiluppi and Michlmayr, 2007].

The evolution of the community is important for the evolution of the system itself, and each contribution affects the system and at the same time has an impact on the profile of the community member who made the contribution [Nakakoji et al, 2002]. Nakakoji et al propose three different classifications for the projects and the community dynamics they involve. They name these categories exploration oriented, utility oriented, and service oriented [Nakakoji et al, 2002]. These categories are not the only types of projects that can be found in OSS, as the authors admit but they do provide some information on the dynamics of communities built around software systems with some specific characteristics.

**Exploration oriented** projects are innovative projects. They are distributed through OSS to stimulate interaction and share ideas through the code in the same manner that scientific research is shared through publications. The quality requirements for these projects are usually very high. These projects are controlled by a leader and there is the risk of splitting in the case of a disagreement between the leader and the majority of the community. [Nakakoji et al, 2002]

**Utility oriented** projects cover some needs for functionality and are built through a combination of existing software. Their goal is to provide adequate functionality, unlike exploration oriented projects who aim to provide solutions of the highest quality. In functionality oriented projects the case of a split is something common and there might be quite a few projects offering the same functionality. These projects compete for community members and the one who gets most of the support eliminates the competitor. [Nakakoji et al, 2002]

**Service oriented projects** aim to offer a stable and robust service to direct and indirect users of the systems. The changes in these systems have to be conservative and carefully planned. The leadership in this project belongs to a core team and the decisions are made collectively. It can be seen as centralised but not revolving around an individual. Most of the community members are passive users in these projects and on occasion active and peripheral developers appear during periods when new functionality is being added. [Nakakoji et al, 2002]

In cases of businesses working as a unit on top of a shared platform by offering their services and products, like the case of growing an ecosystem, the onion model does not provide the whole picture of business partners and their connections [Kilamo et al, 2011].

## 2.6 The Evolution Of Open Source Towards A More Business-Friendly Road

Up to this point, the term FOSS has been used once and the term OSS has been used to refer to this development process. There is however a difference between those two terms. Fitzgerald [Fitzgerald, 2006] argues that OSS has gone through a transformation from its first form where individuals and groups developed a system to

cover their personal needs, to a more business friendly form. This transformation is explained through a comparison of FOSS and what Fitzgerald calls OSS 2.0. The argument here is that OSS has undergone a “deep transformation” but besides describing a growing tendency for taking a business interest in OSS as a new trend, the argument does not seem strong enough to convince that the former drive in FOSS has disappeared as the word “deep transformation” would imply. It can be seen though that a qualitative change has taken place in the wider OSS development community.

The first difference can be found behind the reasons for starting an OSS project. In FOSS projects are based on satisfying some need through the use of the software. The group doing the planning and the analysis is interested in covering its own needs in the first place, and for this reason the most successful FOSS projects have been infrastructural projects covering the needs of a wide group of users [Fitzgerald, 2006]. In the case of OSS 2.0 design and analysis are carefully done, the development is more formal and involves paid developers unlike the bazaar nature of FOSS [Fitzgerald, 2006]. The opening of closed-source proprietary software has created the possibility of success in projects that are aiming to satisfy the needs of a particular group of users [Fitzgerald, 2006].

The second difference is between the business use possible in the two types of projects. In FOSS the business strategies included support services on the projects or using a free and version of a software to increase the market for an alternative proprietary version. In OSS 2.0 a product might be released to reduce the market share of a competitor by offering alternatives to their products. Other business uses are using an OSS product as a platform for adding extensions on top of it, offering services and support, offering a commercial versions through the use of dual-licenses, using the community to extend the software for free, offering training and certification. [Fitzgerald, 2006]

These trends pose challenges for research and practice. The one that is particularly relevant in the context of this work is stimulating OSS development in domains which require specialised domain knowledge for developing a product [Fitzgerald, 2006] such as the healthcare IT domain.

## **2.7 Management Style – The Software Project Governance Framework**

The aspects of OSS that were presented show that there is a variety of participants, of their roles and motivations. Eugenio Capra and Anthony Wasserman [Capra and Wasserman, 2008] provide a framework for evaluating the style of management of an OSS project through the use of four dimensions. These dimensions are contributions, project leadership, working practices and testing [Capra and Wasserman, 2008]. Two types of projects are defined as opposite on all of these dimensions and they are the “traditional closed source projects” and the “completely open”. The framework rating can put a project anywhere between the two of them.

The “traditional closed source project” is led by a company which has complete control over the decisions, and has a defined structure and process which aims to produce a product of high quality on a predictable schedule. The developers are paid by the company and report their progress to the management. Their communication is not open to people outside the company, and most of the testing is done before the product is released. While there might be interactions with the users, all the decisions are up to the company. The users might have a beta version available before the final release of the product and mechanisms to report software issues. [Capra and Wasserman, 2008]

On the other hand, a “completely open” project has its own community which is open to anyone who is interested in participating. The code is available online and can be acquired and used according to the project's license. The group or individual leading

the project decides on the license to be used, on who can make code changes to the project's repository, and when the version of the software should be considered as a stable release. In some projects decisions are made through informal discussions and in others there might be a voting procedure. The participants rarely meet in person and do most of the work through online means of communication. Both volunteers and paid developers are participating but most of the code is developed by volunteers. Imposing deadlines on the developers under these conditions is difficult or even impossible, as opposed to what can be done in commercial organisations. The testing process is done by the community of users who are expected to provide bug reports through the use of online bug tracking systems and provide a solution to the bug whenever that is possible, or this is left up to the contributors. User support is provided informally by other users of the community. [Capra and Wasserman, 2008]

Each of these dimensions has a value from 1 to 4 and the descriptions to these values are mostly qualitative with some involving quantitative measures as well.

The dimension of contributions measures the reliance of the project on hired developers. [Capra and Wasserman, 2008]

Value	Description
1	100% of the code is developed by hired developers
2	>80% of the code is developed by hired developers
3	>50% of the code is developed by hired developers
4	Most of the code is developed by volunteers

*Table 2: Contribution Dimension [Capra and Wasserman, 2008]*

The dimension of leadership measures how formally organised is the project and how open the decision-making process is. [Capra and Wasserman, 2008]

Value	Description
1	Roadmap and development process are led by one company or organization which has a predominant leadership role, makes decisions and sets schedules.
2	Roadmap and development process are led by one company or organization. However, free discussion and participation to the governance of the project is fostered.
3	The community is ruled by some formal rules and principles. Decisions are made mainly by voting or by governance bodies directly elected by contributors.
4	The community completely lacks a formal organization and governance bodies. Decisions are made by informally discussing issues.

*Table 3: Leadership Dimension [Capra and Wasserman, 2008]*

The dimension of working practices measures the extent to which the developers are distributed geographically.

Value	Description
1	Developers work on the same site, communicate in traditional ways and have regular physical meetings.
2	Most developers work on the same site and have regular physical meetings, with some remote participants
3	The community is dispersed and most developers are remote. Some subsets of developers, however, work at the same location and meet regularly.
4	The community is widely dispersed and all the developers communicate through virtual tools. Physical meetings are totally absent or very rare (1-2 per year).

*Table 4: Working Practices Dimension [Capra and Wasserman, 2008]*

The dimension of testing measures to what extent the testing is done through a well-defined internal process or by the community after the release of the software.

Value	Description
1	All the testing is controlled internally by specific QA roles. New versions of the application are released only after being thoroughly tested.
2	Most testing (>50%) is performed internally before new versions of the application are released. The user community is leveraged as a broader testing platform, for example by releasing beta versions and then collecting feedback and bug notifications.
3	Some testing (<=50%) is performed internally, but most of it is left to the community of users.
4	Testing is completely left to the community of users.

*Table 5: Testing Dimension [Capra and Wasserman, 2008]*

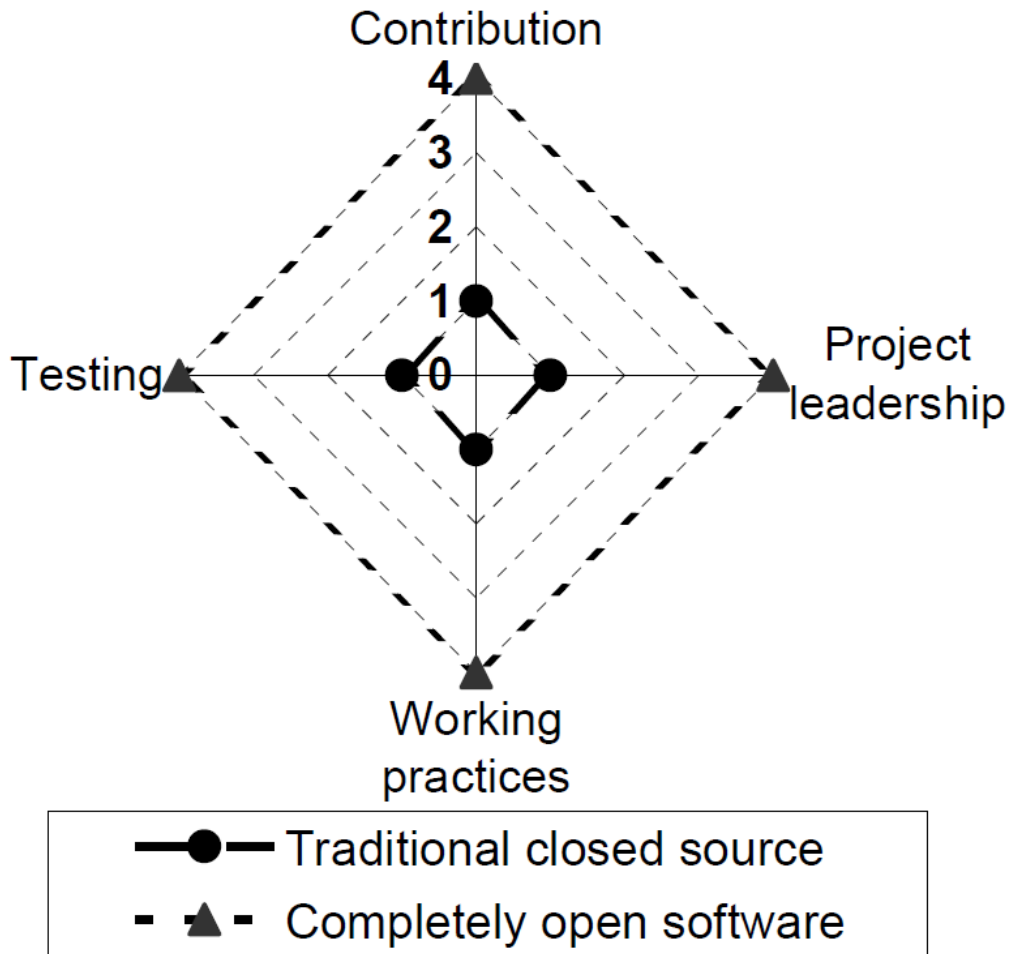


Figure 5: Graphical Representation of Project Classification [Capra and Wasserman, 2008]

The graphical representation of the framework's application can be seen in figure 5.

The framework can give a good picture of the nature and management style of a project. All the types of projects despite their differences in management style are encouraging and appreciating contributions in any form, even simple bug reports, and they give the complete ownership of the project to the community [Capra and Wasserman, 2008], although the extent that this can happen could depend on the driving force behind the project. It is hard to think that a company with an agenda and goals to fulfil, would be unlikely to not pursue some of its strategic goals from the release and give the complete ownership to the community.

Regarding the type of the software, a strict control is important in cases where there is a technical risk associated with the project and is necessary need to separate the core of the software from the user space. On the other hand, a loose control might be more suitable in cases that adding more features would add to the value of the software without imposing risks [Senyard and Michlmayr, 2004].

### 3 Electronic Health Record Systems

During the introduction, the term EHR was used without providing much information about the meaning of the term or the type of system it refers to. In this chapter the ambiguity surrounding the term is presented and a classification that satisfies the needs of this work is adopted, some expectations for the development of EHR systems are suggested and then documented in more detail. The expectations from EHR systems which will receive most attention are those related to strategic approaches for large scale EHR development and the impact of an EHR in the healthcare delivery process itself.

Before moving, information will be presented on the strategies employed so far in different countries and their architectures, we move to a study of some aspects of the EHR systems used in a local setting, dealing with who the users of the system are, what some of their expectations are, what the work environment in which the EHR is applied look like and some related adoption barriers.

Next we will deal with issues related to where the value of EHR is expected to come from, few criticisms of EHR systems, a small overview of the standards used so far, and a summary of the important aspects which have to be considered in the implementation approach and the possible need to reconsider a key element in the strategies employed so far.

#### 3.1 The Term EHR

According to the International Organization for Standardization (ISO) an EHR is a repository of patient data, stored and exchanged securely in digital form, which is accessible by multiple authorized users [Häyrynen et al, 2008]. The information contained in the EHR might refer to the past, the present or the future, and their purpose is to support efficiency, continuity and improved quality of integrated healthcare delivery [Häyrynen et al, 2008].

Moreover, according to the Institute of Medicine (IOM), “An Electronic Health Record (EHR) is a patient record that resides in a computer system specifically designed to support care providers by providing accessibility to complete and accurate patient data, medical alerts, reminders, clinical decision support systems, links to medical knowledge and other aids” [Spil and Katsma, 2007].

We could say that the ISO definition offers a somewhat static picture more focused on the records, while the IOM definition refers to a system which plays an active role in supporting the healthcare delivery process, through the use of features such as alerts, reminders and decision support.

There is a number of terms referring to healthcare information systems, some of which are Electronic Medical Record (EMR), Patient Care Information Systems, Electronic Care Record, Electronic Health Record, Computer-based Patient Record and Electronic Patient Record. The different terms might show different views on the systems or different functionality levels [Spil and Katsma, 2007].

Häyrynen et al's statement that “the meaning of EHR is unstable”[Häyrynen et al, 2008] seems to be supported by the different terms used to refer to similar systems, and the subtle differences between the IOM and ISO definitions. For instance, EMR and EHR have been used in research and practice to refer to the same concept [Sherer, 2011]. It is for this reason probably, that in 2008 it was proposed to use the term EMR to refer to systems used in a local setting, and the term EHR for interoperable systems that are used in more than one organisation [Sherer, 2011]. This was proposed by the National Alliance for Health Information Technology, a USA-based not-for-profit

association of health care providers, information technology vendors, and health and technology associations which ceased its operations in 2009 [Medical News Today, 2009]. In the context of their article, Møller and Vosegaard [Moller and Vosegaard, 2008] use the term 'EHR' to refer to “the patient-centric view of data collected from several source systems”.

The categorization by Kwak [Kwak, 2005] was found to be very helpful in the context of this work. In this categorization the systems are grouped into Local EHR, Shared EHR, Personal Health Records, and Public Health EHR [Kwak, 2005]. Local EHR systems refer to systems which are used in individual healthcare facilities. The shared EHR systems refer to systems covering a number of organizations, facilitating the use of shared and integrated records in different settings. PHR refers to records maintained and controlled partially or completely by the patient. Finally, Public Health EHR refers to aggregated and anonymous patient data, usually used for public health and epidemiological purposes, research, health statistics, policy development and health service management [Kwak, 2005].

The conflicting terms and views regarding EHR systems make it necessary to understand why EHR systems are developed in the first place and what their use is.

### **3.2 EHR Expectations : Why Are They Used?**

Regarding the goals of an EHR project, it can be argued that they are to improve the healthcare delivery process, to speed up administrative processes, to enable and to encourage patient involvement [Häyrinen et al, 2008] with their health and wellness, and providing integrated healthcare services in large geographic areas. All these should lead to improved patient safety, efficiency and quality of healthcare. Secondary uses include evaluation, quality improvement and original research [Noseworthy, 2004].

Administrative processes are facilitated through the support of features such as billing and scheduling [Carayon et al, 2009], and by avoiding errors, duplication and saving time through the use of electronic means instead of paper [Edwards, 2006]. In Denmark for example in 1994 an estimated 20-30% of administrative spendings was used for handling paper [Edwards, 2006].

Patient involvement is enabled by providing access to health information and providing support through applications, possibly for involving the user in chronic disease management which is imposing a burden on healthcare systems [Sherer, 2011] .

Providing integrated healthcare services in large geographic areas refers to the support of continuity and integration of patient care. Lack of patient care integration was mentioned in the introduction as one of the issues the healthcare systems are facing. Allowing unified access to patient information and collaboration between healthcare personnel in large regions is the key in achieving this. This requires a shared EHR system of some sort and shared models of care [Noseworthy, 2004].

The impact on the healthcare delivery process is related to aiding the work process of the healthcare personnel by :

- Enabling evidence based decision making
- Reducing duplication in tests, pharmaceutical management [Noseworthy, 2004]
- Avoiding the inaccuracy and incompleteness of paper records [Carayon et al, 2009].

Next, the aspects of providing integrated healthcare services in larger areas and the impact on the healthcare delivery process will be further analysed.

### 3.3 Enabling Patient Mobility And Integrated Care

Access to electronic records in large geographic areas is the key to enabling patient mobility and continuity of care. It is a very complex matter and different strategic approaches are taken to achieve it. In order to start understanding this, we have to take a look at the strategic approaches and the architectures employed so far, then deal with the issues arising from them.

This section will provide a few information on the strategic and architectural approaches taken by Canada, Australia, UK, Denmark and the Netherlands. The information is not very detailed, but provides a good ground for further reasoning. All the information presented here for Canada, Australia and UK is taken from [Jalal-Karim and Balachandran, 2008] and therefore no citation will be provided below and it should be taken for granted that everything is found there, while the information for Denmark is taken from [Moller and Vosegaard, 2008], and the information on Netherlands is taken from [Spil et al, 2010] and [de Smet, 2011] and will be cited accordingly.

#### 3.3.1 National EHR In Canada

The main characteristics of the Canadian approach is the mainly publicly funded healthcare system since 1968 and the key role of a not-for-profit organisation called Infoway in promoting and speeding up the development and adoption of EHR systems. The goal of Canada is to achieve complete national coverage by 2020.

The funding program for Infoway started in 2002 in order to develop the national EHR strategy, in 2003 it was expanded to include telehealth and it had received a total of \$1.2B Canadian dollars up to that time.

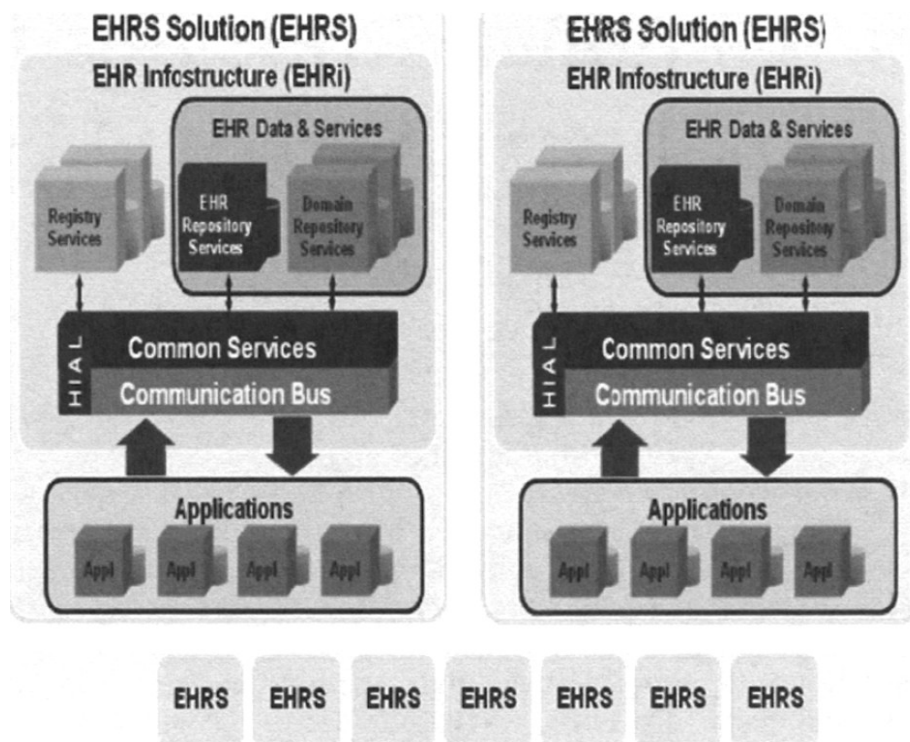


Figure 6 - Canada EHR Solution: Distributed, Message-based, Peer-to-Peer Network of EHRs Systems. [Jalal-Karim and Balachandran, 2008]

The architectural approach can be seen in Figure 6 where two systems are connected through services provided by the Health Information Access Layer (HIAL). The HIAL contains common services, and services for standards and communication, which serve the purpose of integrating the various applications. The next abstraction layer used in this architecture is the EHRI. The EHRI is used for creating or using EHR



content compatible with the HIAL and contains EHR and domain related repositories of information such as medication, laboratory tests and diagnoses. The EHRI is used to “push” and “pull” data from the EHR system.

With this approach the national EHR is a peer-to-peer connected network of local EHR systems, across the whole country, where a user who has access to a local EHR system also receives secure access to information in other local EHR systems through the use of the abstraction layers.

### 3.3.2 National EHR In Australia

In the case of Australia, the e-health agenda has been managed at a national level since 1990. The national strategy follows what is called the HealthConnect Business Architecture, which is aimed at constructing a national health information network and a number of patient event summaries for the use of the HealthConnect system.

The HealthConnect EHR service will involve connection, storage and sharing of patient information in the form of patient event summaries, through the use of a secure network.

The HealthConnect program's role switched from trials and national architecture design to co-ordinating healthcare organisations in order to ensure that they follow the mandatory standards, specification and infrastructure developed by the National E-Health Transition Authority (NEHTA). NEHTA's role is to develop standards and improved ways for secure collection and exchange of information.

The project has followed several stages including research and development for the value and the feasibility of HealthConnect during 2000-2003; research and development for the implementation of HealthConnect such as work on architectural design; and system and data components during 2003-2005; and transition from research and development to national level implementation during 2004-2008.

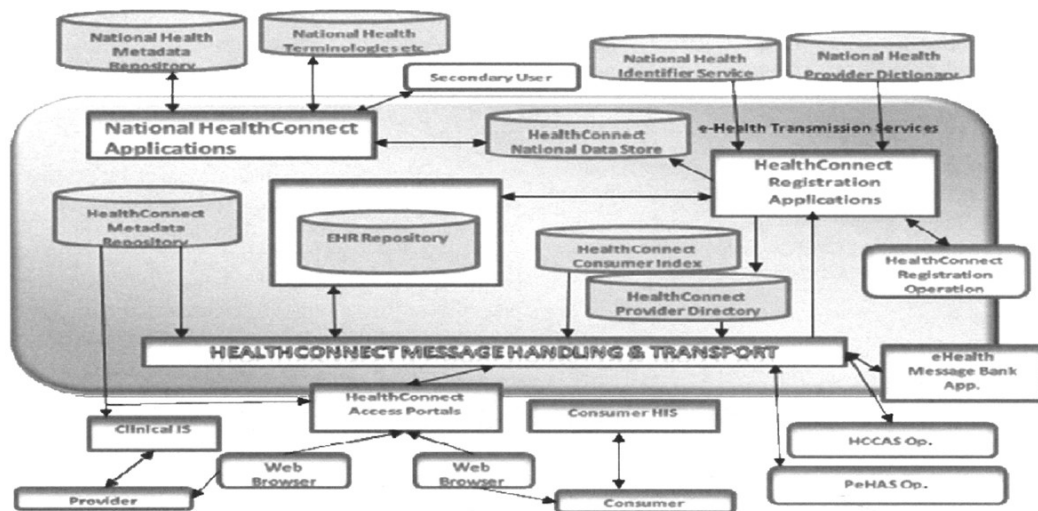


Figure 7 - HealthConnect systems overview[Jalal-Karim and Balachandran, 2008]

The architecture of HealthConnect, as seen in figure 7, is built around a series of event summaries which follow a defined format with metadata, data items and allowed code sets. The summary contains crucial information for issues such as allergies, observations, test orders and results, diagnoses, medication and referrals. The local EHR systems are still used and have to maintain their records. The information will be stored in the HealthConnect Record System (HRS) and the National Data Store (NDS). The HRS provides access to event summaries and the NDS would preserve archival copies of EHR files.

### 3.3.3 National EHR In UK

In the case of UK we are informed that with the start of its national EHR strategy in 1998 the National Healthcare System went through a significant restructuring.

The country was divided into five parts, and each of those parts was assigned a different IT supplier and a different database which could be further divided into two or more parts.

Regarding the strategy, the Department of Health is the entity which created the EHR program structure through an agency called Connecting for Health. The National Programme for IT wants to introduce an integrated system called NHS Care Records Service (NCRS) as seen in figure 8. Development is taking place locally in the five areas into which the country is divided providing various services and the goal is to allow a 24 hour per day, 7 days per week secure access to the healthcare records.

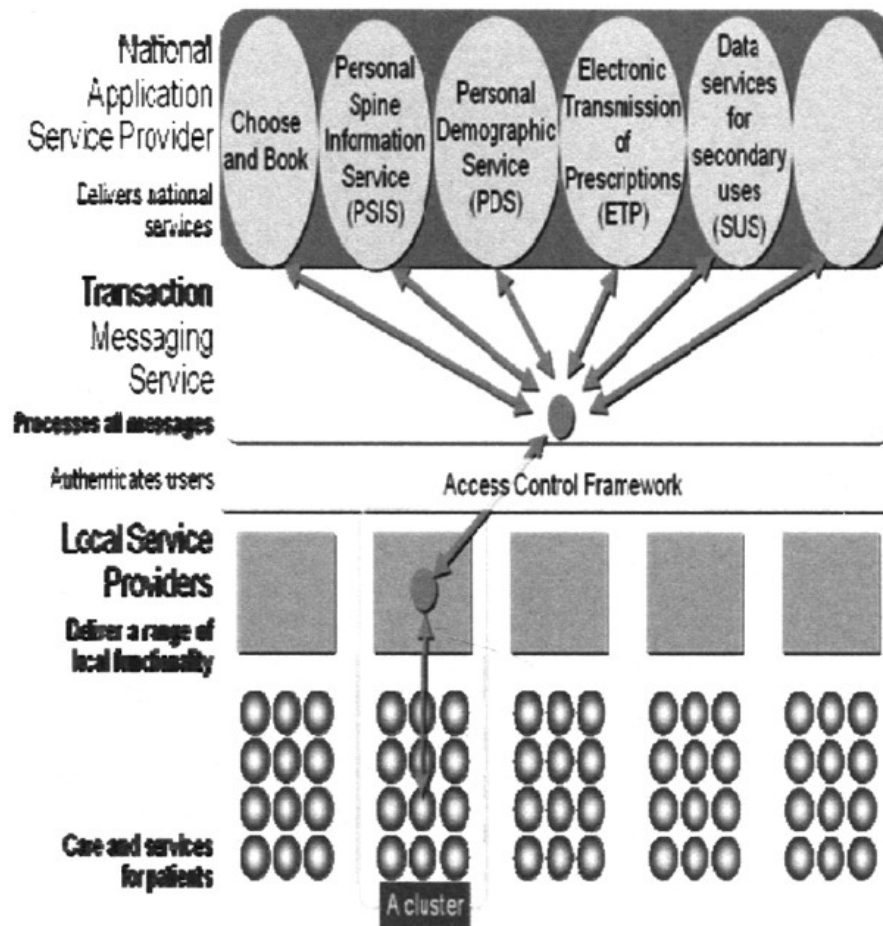


Figure 8 - The NHS NCRS [Jalal-Karim and Balachandran, 2008]

National implementation started in 2003 and contracts were given to one National Application Service Provider (NASP) and five local service providers. NASP is responsible for the implementation and purchase of IT systems common to all the NHS users.

From an architectural standpoint, the NCRS is based on two components : the Detailed Care Record and the National Summary Care Record which is stored in the national database called SPINE. The summary contains crucial data such as NHS Number, date of birth, name and address, allergies, adverse drug reactions and major treatments. SPINE is the central database of Summary Care Records for more than 50 million patients and uses local systems as sources.

### 3.3.4 National EHR In The Netherlands

Moving on to the case of Netherlands, we are informed that around the year 2002, the Dutch Ministry of Health put Nictiz in charge of designing and introducing a national EHR system [de Smet, 2011]. The data will remain in the local EHR systems and the national one will be a “virtual” EHR [de Smet, 2011].

The 2010 Dutch government expected to have an operational national EHR in September 2009, while the previous government expected it to be operational by 2006 and both deadlines have not been met [Spil et al, 2010].

The local EHR systems currently in use are General practitioners Information Systems (GpIS), Out-of-hours clinics Information Systems (OcIS), Pharmacy Information Systems (PhIS) and Hospital Information Systems (HIS) [de Smet, 2011]. IS are used by all hospitals, pharmacies and out-of-hours clinics and nearly all the GPs [de Smet, 2011]. Regional EHR systems were set up, but they usually covered a certain discipline out of the ones mentioned and integration was difficult due to the use of different structure [de Smet, 2011].

In the current Nationwide EHR, by the end of 2010, nearly half of the GPs, out-of-hours clinics and pharmacies and 10% of the hospitals were connected as their systems comply with the messaging standards and can connect to the Health Information Broker (HIB) [de Smet, 2011], confirming what Spil et al [Sherer, 2011] mentioned in their 2010 paper that “only a few of the 110 general and academic hospitals in Netherlands are ready to participate in such an interoperable EHR infrastructure, given the state of their own EHR implementation” [Spil et al, 2010], as 10% can certainly said to be “a few”.

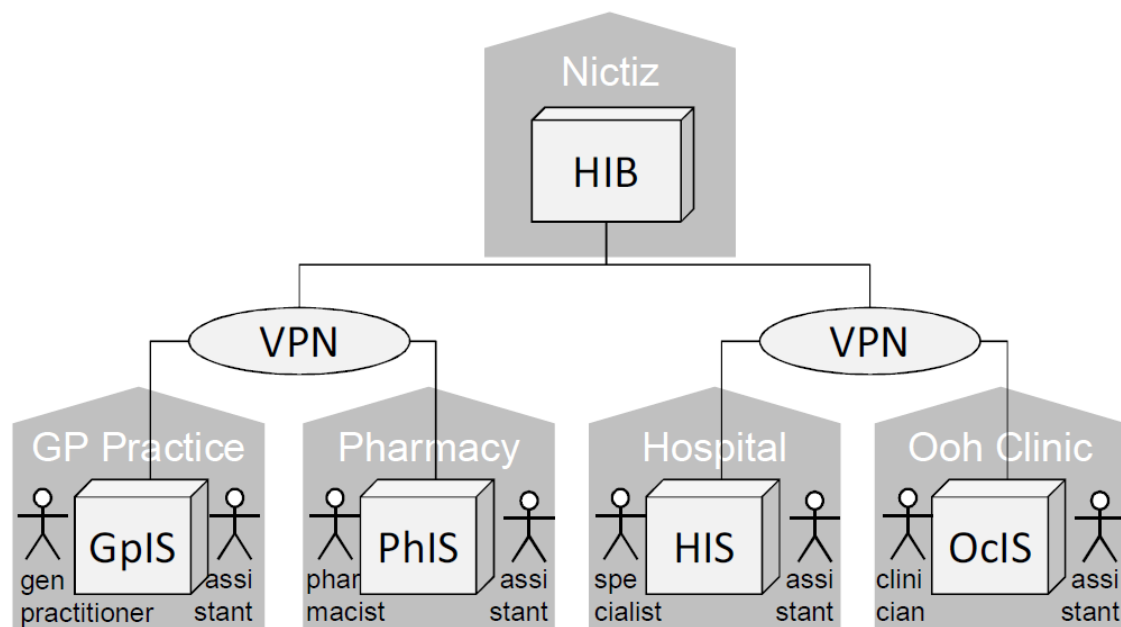


Figure 9 - Dutch Nationwide EHR[de Smet, 2011]

The architecture employed in the case of Netherlands can be viewed in Figure 9, and it is built around the HIB which provides the compound query service (Qry) to the connected EHR systems [de Smet, 2011]. All the information exchange is done through the HIB which controls the access through the National Authorisation Protocol, Record Locator, Access Log and Identification and Authorisation modules.

### 3.3.5 National EHR In Denmark

The Danish EHR is a system to which all hospitals upload extracts on a regular schedule, and is a view of data collected from several systems acting as sources. The data are received by the central database in a custom XML message format from the source systems. The high level architecture can be seen in figure 10.

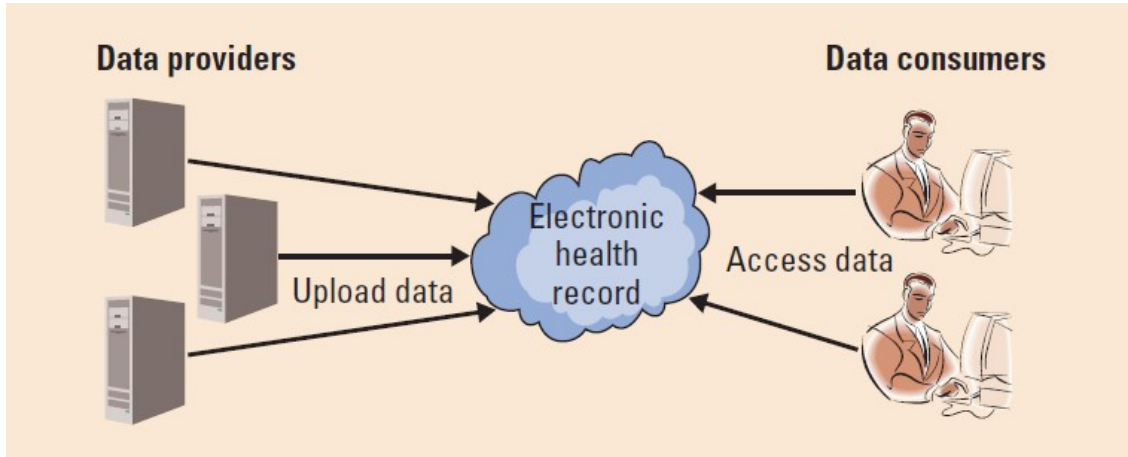


Figure 10: High Level Architecture of The Danish EHR[Moller and Vosegaard, 2008]

The Data Model is made of events which can be arranged or filtered based on criteria set by the user. There are 18 event types and they were identified by clinicians involved in the project. The EHR then uses a relational database between the document store and the applications which acts as a cache with the actual documents stored in the document repository (figure 11).

Therefore a persons record is made up of containers which describe the course of events in a particular medical treatment. The EHR is a relational database containing large parts, is extensible and is updated automatically whenever it is updated by receiving new data in the specific acceptable XML format.

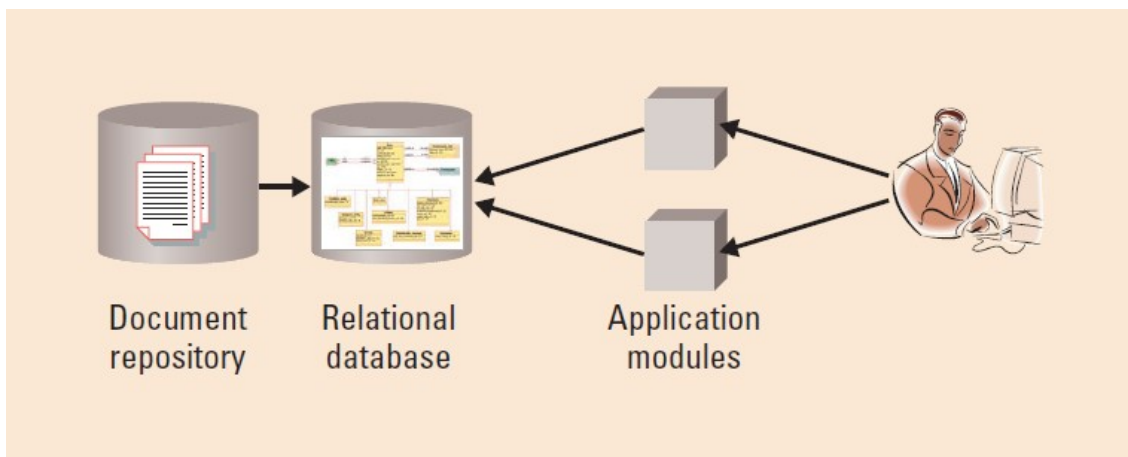


Figure 11: EHR Solution Using a Relational Model for Cross-searching of Document Contents [Moller and Vosegaard, 2008]

### 3.3.6 A Comment On The Strategies

Having seen a few different strategies for national EHR implementation in different countries, we can notice that nowhere in those cases has the national EHR been a replacement for a local EHR system, but rather it aims to connect the local systems to

one another. In the case of Canada this will be done by forming a peer to peer network through the use of abstraction layers and in the other four by creating a system that receives data from various systems and integrates them in its own standards based, data model, which takes the form of extracts and summaries (Australia, UK) or a different one considered more appropriate.

Moreover, what we can see from conclusions of Jalal-Karim and Balachandran [Jalal-Karim and Balachandran, 2008], note that while significant progress has been made in the three countries they presented in their paper, no strategy has lead to a national EHR system. This is also supported by Cresswell et. al. [Cresswell et al, 2012]. Therefore the study of the local EHR systems becomes crucial, as this is the common element in all the strategies. Before we do so, it is beneficial to see some important lessons learned which are related to the implementation strategy.

### **3.3.7 Strategy Related Lessons**

The case study by Cresswell et al [Cresswell et al, 2012] touches some interesting issues regarding national EHR implementation based on the English experience in this. In the case of Denmark we have some information by Møller and Vosegaard [Moller and Vosegaard, 2008] and from Edwards [Edwards, 2006]. In [Edwards, 2006] issues regarding healthcare information exchange in general can be found, some of which are related to EHR systems. As [Edwards, 2006] is included in the references of [Moller and Vosegaard, 2008], references to both for the same issue will be avoided.

The most important pre-requisite for implementation of complex EHR systems was the existence of some system which is used in one setting or could be modified in order to fit the local needs [Cresswell et al, 2012]. This demonstrates the evolutionary character of EHR development. The same is supported by [Moller and Vosegaard, 2008] which states that while a high quality, semantically consistent data is the ideal solution, the initial phases can have much less. We can see that while there was an overall lack of usability in the systems, it was more apparent in the case of previously untested systems [Cresswell et al, 2012].

This evolutionary process has to be respected in all the cases, as ambitious timelines had a negative impact on the process by forcing users to find ways around the use of the system, such as resorting to the use of paper record keeping due to the easier working pattern offered, and updating the system information at a later point. This was due to lack of usability and having systems which did not fit into the local setting. [Cresswell et al, 2012]

The importance of the local level is also mentioned in [Edwards, 2006], where one of the suggestions is to “devote plenty of resources to local implementation and training”, something which is expected to aid adoption, and avoid cases of resorting to the use of paper.

Involving the users through consultations was found beneficial in motivating them to use the system. Regarding the stakeholders in general, the need to align their interests at the national level was observed. The stakeholders also involve developers, who were found to be more interested in financial benefits rather than delivering quality systems. [Cresswell et al, 2012]

There was some tension between the necessity to satisfy local needs and considering standards for interoperability [Cresswell et al, 2012]. If we were to choose between the two, Cresswell et al suggest that satisfying local needs comes first as imposing national systems was considered unlikely to work [Cresswell et al, 2012]. However there is a need to find some balance between the two because if there are no standards, integration of the individual systems would have major risks [Cresswell et al, 2012]. Standards are considered among the critical success factors in [Edwards, 2006]

along with the need for balance between local and central level without any further details on how to find this sort of balance.

A very interesting insight provided by [Cresswell et al, 2012] was that participants argued that the central authority overseeing the implementation should place an emphasis on connecting “local and natural groupings of healthcare organisations” in order to achieve local benefits first, then consider interoperability at a larger scale. The benefits of this approach were seen in Netherlands where Spil et al [Spil et al, 2010] observed that the collaboration of two hospitals lead to improvement of the quality, leading them to suggest a “Network of collaborating hospitals could therefore be a successful path”.

Who pays for the system(sponsor) was also among the important issues. As someone with an interest in funding the development and operation is considered necessary [Moller and Vosegaard, 2008], providing financial incentives for practitioners to adopt local EHR systems [Edwards, 2006], establishing data privacy and security [Edwards, 2006], ownership and responsibility for data integrity and maintenance [Moller and Vosegaard, 2008], as well as the benefit that data providers will get from sharing their data [Moller and Vosegaard, 2008].

We will deal in some more detail with some of the issues mentioned in this section at a later point during the work, after consider the local systems and the local setting.

### **3.4 Local EHR Systems**

Local EHR systems are, arguably, critical if any national strategy is to succeed. They are the common element in all the strategies and none of the approaches presented so far aimed at replacing them with a national system, but instead they aimed at using them along with the national systems. The local EHR systems have an impact in patient care as they directly affect the working patterns of the healthcare personnel.

Therefore, it becomes important to understand more about the context of its use, the profile of its users, the necessary qualities it has to satisfy in order to be accepted by them, what is its relation to the national systems and what is its place in a national strategy.

#### **3.4.1 On The Application Setting Of The Local EHR Systems**

The typical division of healthcare services in different countries is in primary, secondary and tertiary care. The healthcare delivery takes place at the community level, at a specialist facility and at a hospital respectively. At the primary care level, care is provided by general practitioners who may give the patient a referral for treatment at a specialist facility, and at the hospital level care is provided by a team of specialists. [Häyrinen et al, 2008]

These can be public or private sector organisations, hospitals, healthcare centres, specialised units, and to make things more complex, there are different units within those organisations with differences regarding physical, organisational and social aspects. [Viitanen et al, 2011]

The potential users of a local EHR system are healthcare and administrative staff, including physicians, nurses, radiologists, pharmacists, laboratory technicians and radiographers [Häyrinen et al, 2008]. The primary users of HIT, including EHR, are physicians and nurses [Viitanen et al, 2011]. These users should be considered as a heterogeneous group, with differences in skill, needs, interest in using IT systems, work responsibilities, individual working history, specialisation area in medicine, working practices, ways of interacting, and ways of using HIT [Viitanen et al, 2011].

Despite the diversity, their work has one clear goal, which is curing and treating patients [Viitanen et al, 2011]. Despite the simplicity of the statement understanding the

nature of the work is not trivial. Medical work is typically unpredictable with a constant need to negotiate the next action [Faber, 2003], it is concerned with rapid task completion and having access to relevant information [Viitanen et al, 2011]. Exchanging information and communicating are essential parts of clinical work [Viitanen et al, 2011].

The following characteristics have been attributed to clinical work :

- Nomadic work
- Collaboration and co-ordination
- Mobility among diverse devices
- Rapid context switching
- Integration of physical and digital work. [Viitanen et al, 2011]

### 3.4.2 Factors And Barriers Of EHR Adoption

Finding some adoption factors are an important first step to understanding some the necessary qualities that an information system must possess to be successful in its application setting. Spil and Katsma mention in [Spil and Katsma, 2007] that in a previous study conducted by them, which involved a number of EHR users they found five top factors. The study which is was carried out on [Spil and Katsma, 2007], involved mainly physicians in hospitals this time, and found five different factors. Those are shown in the table below in order of importance.

<b>Top Factors</b>	
<b>Physicians</b>	<b>EHR users including physicians</b>
Direct contact with the patient	Availability
Quality of care	Reduced administrative work (letters, search and redundancy)
Collaboration with colleagues	Analyses for research and/or management
Time	Uniformity of working processes
“Just” being a good doctor	Reliability

*Table 6: Top Factors of EHR Systems Successful in Their Application Setting*

Availability and reliability probably refers to information availability and reliability and not system availability and reliability, as the authors mention that those two can be sometimes seen as the opposite of each other, something which is true for information but not system availability and reliability.

What is noteworthy here is that quality of care did not show up when non-physician users were involved. Furthermore, collaboration with colleagues involves those inside and outside of their organisation. The lack of time was frequently mentioned and the “just” being a good doctor refers to them being able to do their job well and provide a good quality of care. [Spil and Katsma, 2007]

Other adoption barriers are presented in the systematic review done by Shekelle and Goldzweig [Shekelle and Goldzweig, 2009] which includes a number of information on them. While the review considers HIT in general, EHR are the most frequently mentioned systems and some of the information are EHR specific. Nonetheless what applies to HIT, applies on EHR systems as well.

The key adoption barriers are cost, perceived difficulties using the system and perceived adverse effects on working patterns [Shekelle and Goldzweig, 2009].

Regarding cost, an editorial included in the review mentions that while significant financial returns are predicted for healthcare systems, organisations and individuals see only an 11% of return on their investment [Shekelle and Goldzweig, 2009]. This would explain why financial incentives serve as an adoption facilitator, and why in the case of Denmark providing financial incentives for adoption was considered a critical success factor [Edwards, 2006], as it was already mentioned. The benefits are correlated with the size of the organisation and its mode of operation, with larger organisations and those operating for reasons other than profit being more likely to adopt an EHR system.

The perceived difficulties in the use of the systems, is related to “perceptions” of adverse effects on workflow [Shekelle and Goldzweig, 2009], something which requires further clarification as “perceptions” is not very precise but if we combine this with the information on poor usability the perceptions are grounded on actual issues. Satisfaction from the systems was strongly correlated with the ability of the system to do things “in a straightforward manner” [Shekelle and Goldzweig, 2009].

Other issues mentioned were system interoperability, concerns about privacy and confidentiality, and the lack of a well trained healthcare informatics workforce to lead the process [Shekelle and Goldzweig, 2009]. Interoperability was mentioned in an editorial, and while it is unclear if it refers to local systems or national ones in this case, the issue of interoperability being intimately connected to the local level and not being something external to it will be evident later when we present an interesting way to look at HIT usability, given by Viitanen et al in [Viitanen et al, 2011].

The study which was the most sophisticated according to Shekelle and Goldzweig and was related to adoption barriers and factors, was a case study done in Sweden. It is important to present it and its findings along with the comments made by the authors on it. The suggested general lessons for implementing EHR according to that study are :

- Saving time for the clinical personnel and a working system for them should be the overriding criteria
- Choose a system which has been used in a similar context, and meets the needs of a range of users
- The system should be intuitive and require little training
- Should be easy to modify and develop for different departments
- The decision process should be participatory until the decision is made, then it should be directed and driven
- There is a need to balance local implementation and clinical participation with meeting higher level requirements
- Involvement should happen in a structured way, with defined roles and responsibilities, regarding issues that require local decisions, or higher level decisions like standards for example
- Make use of adoption factors and barriers shown in research, by assessing their presence or absence. [Shekelle and Goldzweig, 2009]

Important as those suggestions are, we have to examine them in a little more detail, as they can reveal some difficulties in their application. Saving time for the clinical personnel, reinforces the importance of the “time” factor mentioned in [Spil and Katsma, 2007].

Choosing a system that has been previously implemented was also mentioned in [Cresswell et al, 2012], but as Shekelle and Goldzweig [Shekelle and Goldzweig, 2009] note, there is a very limited information about the context (“very small” and “tiny” used to describe the amount), the evidence about saving time, and what “works for clinical personnel”, all of which don't make it easy to make such a decision.



The system should be easy to modify, intuitive to use and require little training. These are concrete system characteristics. The first refers to modifiability, most likely to support evolutionary development which was found necessary in other cases, and the second to system usability. Although defining what is “intuitive” use for a diverse group of users like healthcare personnel might be challenging as other factors such as cultural differences and previous experience with EHR might come into play in this.

The other factors relate to the decision making process and the need to connect the local system with the national strategy (“higher level decisions about standards”), and using the experience from other cases, as it is presented in literature. Of course this requires the pre-existence of some sort of standards or higher level coordination in which the local EHR is one part of it.

Many issues of adoption raise the question of usability and time effective use of the systems. It seems that it is increasingly important to understand usability in HIT. Furthermore, a somewhat closer attention has to be paid to the user involvement and the decision making process.

### **3.4.3 A Systemic View Of Usability And Some Possible Implications**

Viitanen et al [Viitanen et al, 2011] present a very interesting and well documented way to approach usability of Information Systems in healthcare. Their approach, which is based on the ISO definition of usability, looks at usability by using three dimensions and making a strong argument that evaluating usability requires more than assessing the efficiency of human-computer interaction by using traditional means. It is a systemic because it provides an integrated view of usability through the three dimensions they use to explain it and provide insights on how these dimensions are connected.

The first dimension is “Compatibility between ICT systems and physician's tasks”. The primary goal of the users is to take care of, and cure the patients. HIT systems have to be integrated into physicians' working processes instead of forcing them to adopt new processes or perform additional tasks. This would mean allowing efficient task performance through appropriate functionality and intuitive user interfaces. Towards this direction clinical documentation takes a significant amount of time and is the “one of the most challenging bottlenecks”. [Viitanen et al, 2011]

The second dimension is “ICT support for information exchange, communication and collaboration in clinical work”. Since the working process in healthcare delivery requires a high degree of collaboration and cooperation, and the dominant attributes of this work are information transfer, coordination of activities and communication among the healthcare workers, support of multiple users and their working process is something essential for EHR systems. [Viitanen et al, 2011]

The third dimension is “interoperability and reliability”. The issue of interoperability and integration of separate HIT systems has not been solved, and is important regarding usability. It has been shown that when devices and HIT systems lack interoperability the workflow of the healthcare professionals is slowed down. Moreover, the safety critical use context demands that these systems are reliable. In order to satisfy the physicians who want reliable systems that fit to the existing technology environment, technical feasibility seems to cover integration, information flow and compatibility between systems, applications and technologies. [Viitanen et al, 2011]

In section 3.1 some observations were made regarding the term EHR, one was the interpretation of EHR according to the ISO definition and the other was the IOM definition of EHR. What is interesting here is that assessing the systems through the first and second dimensions seems to challenge the idea of the EHR being simply a *“repository of patient data, stored and exchanged securely in digital form, which is accessible by multiple authorized users”*, while the IOM definition that *“an Electronic*

*Health Record (EHR) is a patient record that resides in a computer system specifically designed to support care providers by providing accessibility to complete and accurate patient data, medical alerts, reminders, clinical decision support systems, links to medical knowledge and other aids*” seems to provide some guidelines regarding the functionalities to support certain tasks (as the first dimension requires) but doesn't have any considerations regarding support of collaboration and communication (as the second dimension requires).

Important as they might be, the first and second dimension keep the considerations for the HIT systems used in clinical practice, and by definition the local EHR as well, internal to the system and its direct environment as the system has to support the physician's tasks, the information and collaboration of multiple professionals.

The issues raised by the third dimension are more far reaching though. Interoperability which was previously a consideration at the national level in the “conflict” between local and national level needs, can be viewed as internal to the local setting. This further increases the significance of the local EHR in the national strategy and maybe it shows the need to consider the structure of individual local systems carefully during the national plans.

#### **3.4.4 Standards And Interoperability**

At this point health information is stored in different kinds of proprietary formats in different health information systems, which results in severe interoperability problems [Eichelberg et al, 2005].

For this reason a number of standards have been proposed in order to provide a remedy solution to this problem. Some of the standards are XDS, HL7 version 3, openEHR and EHRcom. Most EHR standards are currently evolving and there is a trend of harmonising and unifying previous EHR developments [Eichelberg et al, 2005].

Conformance to one of the standards or to a combination of them will not solve the interoperability problem according to Eichelberg et al[Eichelberg et al, 2005] as the authors do not believe that all healthcare organisations can reach a consensus on using the same standards. If, however, a large number of organisations use the same data format and agree on an exchange protocol, there seems to be no reason why their systems cannot be interoperable. This seems to be the idea behind XDS where the communicating parties agree on document format, structure and content before the exchange [Eichelberg et al, 2005].

The issue of conformance to standards seems to be more related to the HIT development industry rather than healthcare organisations and this is supported by the opinion expressed by Møller and Vosegaard [Moller and Vosegaard, 2008] where interoperability problems are attributed to a few systems complying with standards. Achieving interoperability at a large scale, despite its complexity, seems feasible from a technical perspective, but is also affected by political and competitive issues [Sherer, 2011] and seems to require a serious amount of co-ordination.

#### **3.4.5 Current Local EHR Systems In Two Countries**

In [Shekelle and Goldzweig, 2009], Shekelle and Goldzweig refer to a number of healthcare organisations as the HIT leaders. These organisations have more than 20 years of experience using HIT systems and were among the first to adopt multi-functional EHR systems. Work on the review update [Shekelle and Goldzweig, 2009] started in 2007, and the previous review was done in 2005. During this period the HIT leaders had continued publishing studies demonstrating possibilities and limitations of real-world EHR application. [Shekelle and Goldzweig, 2009]

The problem with the studies of the HIT leaders is that, excluding one of them, their systems are not commercially available and were developed over the years, in a process of co-evolution, they were adapted to their local environment and work processes, and the process was lead by a local champion. The “intervention” in this case includes the system and the local champions. This provides little help or information for organisations that want to develop an EHR from scratch and in less time. Furthermore it is challenging to calculate the cost of development as a whole as this took place over several years. [Shekelle and Goldzweig, 2009]

Besides the HIT leaders, Spil et al [Spil et al, 2010], Spil and Katsma [Spil and Katsma, 2007] provide some information on the state of EHR systems in Netherlands and Viitanen et al [Viitanen et al, 2011] have conducted a national survey on usability, where usability in HIT is defined by using the three dimensions that were previously presented.

Spil et al studied the systems in 12 hospitals in the Netherlands using the criteria of quality, value and participation [Spil et al, 2010]. Quality is analysed using the dimensions of information quality, system quality, and service quality. Value is analysed using the dimensions of expectations and subjective norm. Participation will be discussed later. More details on these dimensions are provided in Tables 7 and 8.

Among the 12 hospitals, only two consider the quality of their EHR as high, with one of them having a self-made system which was developed over a period of ten years in an evolutionary manner. What is surprising though, is what the authors mention about the quality of the other systems : “The other hospitals have a double system because the reliability and completeness of the digital system is too low”. The user friendliness seems to be a problem in this case. Concerning service quality, availability which is a key issue for hospitals in their efforts, has not been enough to convince the end users. [Spil et al, 2010]

<b>Dimension</b>	<b>Items Identified</b>
Information Quality	Completeness, Data accuracy, Legibility
System Quality	Ease of use, time savings, reliability, workflow support, interoperability, customization possibilities, expression power
Service Quality	Availability, support, responsiveness

*Table 7: Quality Dimensions in [Spil et al, 2010]*

In the case of value, the subjective norm is too low in most cases and the professionals are not motivated to invest their time in a new EHR [Spil et al, 2010]. This was not the case in three hospitals [Spil et al, 2010]. One of them developed its own system, and the other two being small in size, followed a bottom up approach acknowledged by the top management [Spil et al, 2010]. In hospitals with high expectations, the presence of either a strategic plan or “a group of very enthusiastic doctors” was found [Spil et al, 2010]. What is interesting is that in the cases of an organisation developing its own system, the value and quality are high. Furthermore the “group of very enthusiastic doctors” seems similar to the local champions in the cases of HIT leaders.

<b>Dimension</b>	<b>Items Identified</b>
Expectations	Performance expectation,organizational impact or macro-relevance
Subjective norm	Relative advantage, perceived usefulness, micro-relevance, involvement

*Table 8: Value Dimensions in [Spil et al, 2010]*

The systems only offer administrative value so far, and as the authors put it : “[our] review shows that suppliers fail to deliver the necessary solutions that can support healthcare professionals individually as well as institutions” at the same time when other similar solutions have been offered in similar cases in other domains. [Spil and Katsma, 2007]

These two sources seem to provide a picture of the state of the systems in Netherlands which cannot be seen as satisfactory. In the case of Finland there is also a number of findings with some very interesting implications regarding further development work on EHR systems and their current performance. The national survey done by Viitanen et al. in [Viitanen et al, 2011] had 31.3% response rate with a total of 3929 respondents.

One of the findings of the survey was that the systems have to provide better support for managing patient information, provide specific features like a better patient treatment overview, decision support and medical error prevention, as well as better support for collaboration. [Viitanen et al, 2011]

Support for collaboration between physicians in the same location is considered satisfactory while there is a problem with collaboration between physicians and nurses, physicians and patients and physicians in different locations, with the 2/3 of the respondents considering that the EHR takes the attention away from patient care. There was also a difficulty in accessing patient information documented in different organisations but the specific reasons for this were not analysed in the paper. [Viitanen et al, 2011]

Regarding interoperability and reliability, the results show lack of integration between EHR and other systems and the existence systems failures. An amount of 1/3 of the respondents considered that system malfunctions had caused a risk to patient safety. This opinion is at 43% among respondents in public hospitals, 28% among respondents in healthcare centres and 15% in other organisations which in this case are mostly clinics with a specific area showing a more narrow and well-defined application context [Viitanen et al, 2011]. This raises question about the suitability of the current systems in specific contexts, something which the authors comment on in more detail and support that further work has to be done in order to examine if there are differences inside different units in the same organisation as the systems that were examined were less suited for hospitals than other settings [Viitanen et al, 2011]. This would also be beneficial as it could lead to a better definition of the “local context”, something that was quite often stated as necessary for the systems to support but its implications in system design or the strategy as a whole were not given any further attention besides this statement.

The results of Viitanen et al [Viitanen et al, 2011] that are supported by previous studies are difficulties in data entry, and integration problems between EHR and other systems. They were however contradictory regarding the positive feedback given on the intuitiveness on user interfaces, something which according to them raised question about the suitability of the questionnaire and the ability of the users to evaluate systems they have been using for a long period of time. [Viitanen et al, 2011]

The results from these two countries seem to indicate that the local systems have been unable to have a considerable positive outcome and have caused some problems as well. In the case of Netherlands a self-made system was considered as high quality and in Finland organisations with a very specific application as well as healthcare centres are doing better than systems used in hospitals, showing an inadequacy in the connection between systems and context and a need to do so. Overall the two countries shared similar problems.

### 3.4.6 Cost Related Studies

Cost was seen as the one of the most significant barriers in the adoption of EHR and especially in individuals and small organisations. Shekelle and Goldzweig [Shekelle and Goldzweig, 2009] found that most of the studies were predictive analyses based on many assumptions while their empirical data is limited, something which reduces their value.

The benefits on cost were the greater in multi-functional EHR in large organisations, with a positive relationship existing between the quality of the implementation and the positive effects on the cost. [Shekelle and Goldzweig, 2009]

However, this does not provide any information regarding individual practitioners and small organisations, and no such studies were found by Shekelle and Goldzweig [Shekelle and Goldzweig, 2009]. Another issue of concern is that the analysis did not include implementation costs, which can be as high as 150% of the cost of the system [Shekelle and Goldzweig, 2009]. If this is combined with the information about the challenges in the use of the systems posed by their relatively low quality, then the positive effects on costs are unlikely and the implementation itself is quite costly as well.

Shekelle and Goldzweig [Shekelle and Goldzweig, 2009] also note that there is some empirical evidence to support the economic benefits of EHR or EHR components, realising the benefits would require a coordinated approach in healthcare finances, strong leadership, effective strategies and effort on adapting the systems. [Shekelle and Goldzweig, 2009]

Cost benefits are very context dependent as well [Shekelle and Goldzweig, 2009] showing the need for a coordinated approach regarding the implementation of the EHR strategy which is seen as a whole and not just from the perspective of EHR systems, local clinics or national systems on the other hand. The case of the U.S. in which has a multi-payer system and competitive forces are at work, a low and slow adoption is seen, with studies done in 2008 and 2009 estimating the adoption rates of basic systems at 13% and 20.5% accordingly, and that of fully functional systems at 4% and 6.3% accordingly [Sherer, 2011].

### 3.4.7 The Implementation Process And The Role Of User Involvement

The case study presented by Shekelle and Goldzweig [Shekelle and Goldzweig, 2009] in the Swedish hospital, whose results were presented in the “Factors And Barriers of EHR Adoption” section, we saw two points regarding the issue of user involvement :

- Involvement should happen in a structured way, with defined roles and responsibilities, regarding issues that require local decisions, or higher level decisions like standards for instance
- The decision process should be participatory until the decision is made, then it should be directed and driven.

Spil et al [Spil et al, 2010] analysed participation through the use of the Responsibility, Influence and Process dimensions. It is important how they distinguish between user involvement which is subjective measure and participation which is a set of behaviours and activities done in the implementation process [Spil et al, 2010]. The results of their analysis are more or less in agreement with the two statements given above, like defining precise roles and responsibilities of the participants and that participation from one point and on can hinder the decision-making process [Spil et al, 2010], and they provide some interesting insights as well.

Dimension	Items Identified
Responsibility	Degree and content, level, Overall responsibility
Influence	Decision process, User IS relationship, Influence
Process	Extent and format, Hands-on activity, efficiency & atmosphere

*Table 9: Participation Dimensions in [Spil et al, 2010]*

Spil et al note that participation of both the management and the physicians is important at the first steps of the implementation. The management should keep track of the whole implementation process, and they should encourage the use of EHR systems by doctors and nurses [Spil et al, 2010]. High involvement of users is recommended as this has happened in the cases of hospitals with self-made systems [Spil et al, 2010], and it can be assumed that they suggest this because the most successful cases of EHR systems in hospitals have been with self-made systems. The most important part is that they could not draw a direct link between system quality and participation [Spil et al, 2010].

What all this could mean is that while participation is relevant and necessary, it has been loosely defined and is treated as a solution to improve system quality. While it could be necessary, it has to be well structured and should allow for a versatility in the decision making process, allowing the voice of the user to be heard and taken into account and simultaneously allowing a responsible individual or team to make the final decision.

Another matter that could be loosely considered an issue of participation is the transfer of experiences in EHR implementations. Shekelle and Goldzweig [Shekelle and Goldzweig, 2009] pointed out in the limitations of their study, that while there have been reports of problems with HIT implementations in the press, no studies were published and this is something that has to be encouraged more. As it was mentioned already this could only be very loosely related to participation, since it might not be relevant from the point of local implementation but on a higher level it could be useful as something happening between collaborating organisations.

### **3.5 Where Is The Value Of EHR?**

Having seen the various aspects of an EHR system, it would be rather obvious to question why would an organisation undertake such an effort at the current stage of the implementations. The EHR is valuable to document, follow and monitor the treatment of a patient and to follow the delivery, outcomes and costs of care. All actions and outcomes of care periods/visits are documented to protect both the patient and the health professional. Besides these issues, Sherer [Sherer, 2011] provides a good starting point to understanding this problem at different levels.

Sherer [Sherer, 2011] is of the opinion that benefits can occur if there are high adoption rates and changes in the healthcare delivery process. The introduction of a system can enable new capabilities which can be better exploited with complementary changes in organisational structure and culture, including roles and responsibilities [Sherer, 2011]. This seems reasonable and as it was mentioned before, the leading institutions have taken part in a process of “co-evolution”. The term “co-evolution” implies that, gradual changes have taken place in a two-way manner. Furthermore the high level of adoption and interoperability is a pre-requisite for enabling patient mobility so the assumptions seem safe to make.

The value projections assume the sharing of data between organisations, and the interactions between the different organisations is the place where the value of EHR is

created [Sherer, 2011]. It is necessary to understand where value is created and how the relationships between communicating parties need to change [Sherer, 2011]. From a strategic point of view this implies that the particular data sharing has to be established first and afterwards the way that different organisations will participate and consider how this new situation of data sharing has to change to increase the created value.

Sherer [Sherer, 2011] suggests that research for value creation has to take place at three different levels. The first one has different parties within the same organisations, the second one has independent physicians sharing information with hospitals or labs and the third one is about the interactions between competitive health networks [Sherer, 2011]. The role and value of these levels will most likely vary between different countries, since in a country with a pre-dominantly public healthcare sector in which individual practitioners and private institutions are limited, it cannot be considered important to know the elements of interaction between organisations competing with each other and on the opposite side, a country with a predominantly private healthcare sector made up of a number of competing healthcare organisations would have very different needs. A form of this argument also came up before when the results of the national survey by Viitanen et al in [Viitanen et al, 2011] were presented, and it was suggested to do research in order to find if there is a difference between the suitability of the system in different units within the same organisation, as something that would affect system design.

Next in the argument is the concept of IT embeddedness which refers to the integration of IT with the process to an extent that it becomes essential to it [Sherer, 2011]. This requires changes in workflow and organisational structure and culture whose cost might exceed the benefits, requiring careful analysis, commitment and management [Sherer, 2011]. This is in line with the systemic view on usability through the use of the three dimensions in [Viitanen et al, 2011].

The last part is the creation of an information mindset where various ways of using the information to provide additional value, such as the use of historical data of the patients that would aid in improving the overall quality of care [Sherer, 2011].

While giving answers to the specific questions of EHR value creation is beyond the scope of this work, it is beneficial to take those into consideration when thinking about a strategy that attempts to integrate different implementation aspects.

### **3.6 Chapter Summary And Implications For A Strategic Approach**

In this chapter we looked at the term EHR and some reasons behind the diversity in the terms used to describe systems which more or less have the same purpose. In doing so, an existing classification was adopted for the purposes of this work in which the relevant systems were the Local EHR and the Shared EHR.

Moving on next, the reasons for the use of EHR systems were thought to fit in four themes. Two of those themes, namely enabling patient mobility through national EHR systems and improving the work process of medical personnel through local EHR systems were examined in more detail.

The strategies on national EHR implementation in Canada, Australia, UK, Netherlands and Denmark were presented. A common element was identified in all the approaches, and some “Lessons Learned” related to national implementations found in literature were presented.

Afterwards an overview of the various factors affecting the local EHR implementations was presented. This overview included the environment and the users of the local EHR systems, factors and barriers to local EHR adoption, an interesting view on usability which has implications about the split between local and national EHR systems, a part on standards and interoperability, the state of current local EHR

implementations in two countries, some criticisms regarding studies done on cost, and we took a look at user involvement in system implementation.

In the end, some issues regarding the value of the EHR systems were presented as they were considered by Sherer [Sherer, 2011] along with some comments on them. Through this attempt to view the implementation as a whole, it seems reasonable to support that :

- EHR development, either national or local, is an evolutionary process and it is necessary to have an incremental and slightly conservative approach when implementing projects
- The specific architecture for the national system to fit the specific conditions will vary, however the use of local systems is not replaced by the national systems and this implies that the national strategy has to be heavily involved in the local systems as well.
- The local systems are not only the common part, but they also seem to be the most important part in order to have a successful national system
- Non-profit organisations seem to be used with some success in various countries to implement eHealth projects, EHR systems being among them, and this could be related to their funding which implies actual implementation power
- The balance required between interoperability and usability concerns, in order to meet the needs of local systems and national systems while it seems logical from an isolated perspective, when looked from a more integrated approach is more complex as poor interoperability results in poor usability, something that further connects national and local implementations
- The use of the same or similar systems in different settings has yielded different results, implying a need to look deeper at the various departments in healthcare organisations to see how this diversity in the background of medical personnel affects the needs of the system use. Natural groupings were suggested as a way to cooperate during the development of the systems
- Cost is a tricky subject as most studies are predictive and they do not include implementation costs which can be high. A way to increase the scale of application and coordinate the efforts could reduce spendings
- Who funds the systems is very crucial
- How value, financial or not, can be created from EHR is a complex topic and depends on the structure and the relationships of the healthcare delivery system, in small or larger scales
- It is necessary to establish a legal framework regarding privacy, data ownership and data maintenance in order to be able to have accountability. The legal framework is a limiting factor in the scale of an effort as it affects the design elements of the system.

The next chapter supports the use of -based development for local EHR systems as the part of a large scale EHR implementation strategy and why to consider this as a creative approach to using OSS development in the field of eHealth.



## 4 Using Open Source For An Effective EHR Development Strategy

### 4.1 Introduction

The main goal of this work is to suggest an approach to applying OSS development for bringing changes to the development of EHR systems, and overcoming some of the major problems found in this domain, as they were presented in the previous chapter.

The first step to examine this possibility, was to find the most important software quality properties for EHR systems and some adoption barriers and then see if software produced through an OSS process had a high rating in those properties and was able to aid in overcoming those barriers [Merruko, 2012]. This step showed that there is some potential validity in this question. A more detailed presentation of the indications of potential benefits and challenges of using an OSS development model for EHR systems was given in [Merruko et al, 2012]. In this chapter this argument is presented in its final form in the context of this work.

The evolutionary approach of developing an EHR system with a local champion leading this effort, seems to be the most effective one for developing high quality system. However this does not seem applicable in all the organisations and in the case of individual practitioners who want to use an EHR system. As one of the responses in a study put it : “it takes an army to build and maintain the system, assuming you have not hired the vendor to do this work” [Shekelle and Goldzweig, 2009]. Stating this in a provocative way, OSS is the way to build that army in order to serve the community of users.

This chapter does not present a complete process but an outline covering the main issues and sets the basis for further examination of this question. Although a more thorough analysis is possible at a theoretical level, the question of the positive role of OSS to overcome the problems in EHR systems can only be answered through its application in the real world. The possible benefits and general directions for such an effort are based on the analysis presented on the previous chapters on OSS and EHR systems.

The proposed approach is :

1. *A combination of strategy for building the community and connecting healthcare organisations and individuals or groups of professionals offering healthcare services*
2. *An OSS process for developing local EHR systems.*

The sections that follow are listed in an order of importance and they all should be seen as a unit for a proposed new approach to managing this problem.

### 4.2 Creating A Network And Setting Up A Releasing Authority

The strength of the OSS, like any other approach should be viewed as rooted outside the development process itself. The effort should start by gathering participants from individual practitioners and healthcare organisations, and grouping them for the upcoming effort. Creating the proper groupings and setting up a collaborative network for this effort would probably lead into a higher quality of the future systems, something that has been show in research as presented in the previous chapter.

What constitutes a proper grouping and how their relations are structured is a complicated issue and this work cannot give a well documented answer to that as it is outside of its scope, but intuitively that could be organisations having similar application areas. In the case of Finland for example the systems found in hospital settings were not satisfying their users as much as the systems found in specialised

private clinics. The grouping then could be based on the context of work, like hospitals, healthcare centres, individual practitioners, according to the structure of the national healthcare system and then further subdivided in subgroups based on the departments inside the hospitals which could communicate with other groups in the same organisation and similar groups in different organisations. The existence of an OSS community would show during the process of its evolution how appropriate the grouping is, however what is required for setting up the network that would be the base of this community is that information, leading us to a circular logic. There can be no perfect solution upfront and incremental approach could be more appropriate, leading to changes in the structure of the network over time.

After this network has been set, a trusted authority should be set as the responsible for the release of the software and the coordinator of the network. This suggestion is based on the lessons drawn from UK's implementation. The role of the authority should be to check the software and assure its quality especially on privacy and confidentiality which are the most important aspects for healthcare systems. Besides the assurance this authority will also oversee community processes and employ the core team developers for the project, and will direct the project.

Setting up a non profit organisation for acting as the release authority could be a realistic approach. This is what various countries have done so far to promote the use of HIT. The organisation should have some sort of government funding as this has been the case in the successful projects.

Once these steps have been taken, there is a basis for developing and distributing the EHR systems as , with the organisation acting as the releasing authority of the OSS systems. The reason why this is considered the basis is that even in the absence of an OSS development effort this provides a way to exchange experience on the use of the systems and grow as a community through failures and successes. The strength of OSS development is that it gives power to the users to decide the course of evolution of the systems.

Normally the transition phase and the community watchdog phase are followed after the core team has developed the software and is ready to release it to build the community and aid its growth. However, this approach considers that setting up a network with an interest in cooperatively developing systems and sharing information would create a better approach and would allow calculating the costs and benefits of an upcoming shared development effort. This would allow for better risk management.

This would also aid value research, as the basis for data sharing would be set and the communication between the organisations will create the conditions to understand and express their interests and where do they aim to extract value in this process.

The network should be funded by the institutions and the healthcare system (or systems in the case this happens across many countries). Moreover, the coordinating organisation should have some authority. This is based on the conclusions of the review by Shekelle and Goldzweig [Shekelle and Goldzweig, 2009].

### **4.3 Choosing A System As A Starting Point**

When the implementation effort starts it is better to choose a system that is already used in some context or can be made to work in a different context through some modifications. The groups that emerged from the process that was described as necessary in the previous section, will inevitably have organisations in the same groups operating on the same work contexts. Because of this similarity in the context of the work setting, the same system can be used by them possibly with different configurations.

At this point of course there can be a counter argument in this for the big differences that the users will have even when the context is the same. If we are talking about a general hospital for example, the physicians are different from nurses and even in their ranks the individuals can have a great variety of backgrounds. The users though are active agents and they should be empowered and given responsibilities so that they can spot the problems in the systems or the work processes, and share them across the groups something that will benefit the community and the systems as well. The section on the value of EHR systems that was presented in the previous chapter should demonstrate why this is important. This allows for eventual “embeddedness” of the systems in the process, the creation of new capabilities and work patterns through the use of the systems.

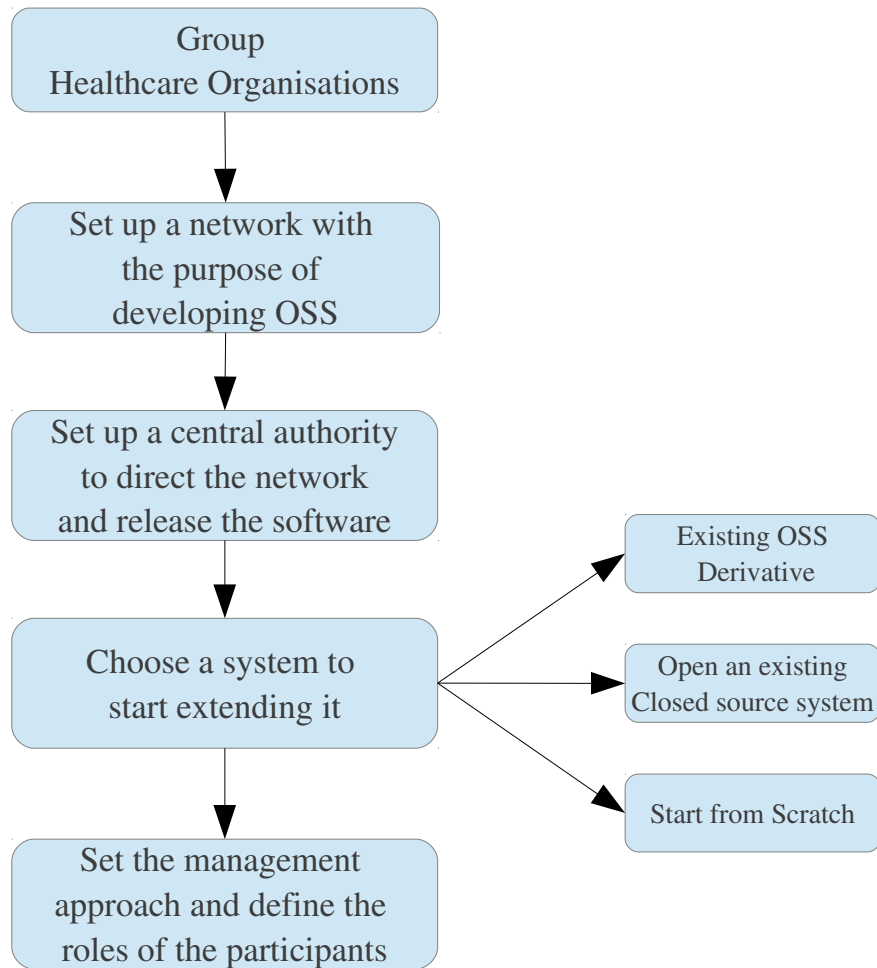


Figure 12: The Suggested Approach

The options regarding the choice of the systems would be creating a derivative work from an existing system if its licence is permissive and allows use of its parts under another license, opening the source code an existing closed source system and using it as a basis for further development, and the final is creating it from scratch. Using an existing system would not allow the evolution of the system and the process to be directed by the network's coordinating authority, so it should not be considered in this approach. Further comments are not necessary in the first case, however the other two require some clarification on some of their aspects. The case of opening the source of a closed system seems one of the most attracting choices as the currently most successful systems could be used. In the case when the healthcare organisations own the rights to their systems and no competitive relationships exist between them and other hospitals, opening an existing closed-source system is relatively simpler than the more complicated case where the rights are owned by a company or when the healthcare organisations operate in competition with one another. The issues that are necessary in

the case of opening the source of commercial software have been mentioned in the OSS chapter, and are rewriting parts of the code and clearing intellectual property rights.

The coordinating organisation should be the releasing authority as it has to guarantee equal access to all participants and have the ability to direct the development. Starting from scratch, even though it is possible, seems to have many risks and should not be attempted as the other choices are safer options.

In every case the system design must be modular to allow contribution and concurrent work from different members.

Another issue that comes up here is the use of different systems from different groups. These should use the same data format and the possibility of a product line should be seriously considered. The reason for this is that the product line approach allows for a common core to be used and variations to happen in the periphery. This lowers the costs and creates a basis for interoperability between the systems.

Using the same standards across different groups in case different systems are considered more appropriate for different groups, establishing a very similar user interface among the systems, and having a modular design are crucial. The first is necessary for interoperability between the systems, the second should reduce the need for the users to learn different systems if the interfaces are similar, and the third would allow concurrent development and extension of the system by the community.

All these possibilities are important for nationally or regionally used systems. Interoperable systems can have a positive impact on usability and possibly a positive impact on financial figures, the similar interface allows healthcare personnel to have shorter learning time for different systems aiding usability and increasing their ability to adapt to a new workplace in case they change jobs.

#### **4.4 How Open The Project Should Be – Issues Of Community And Management**

So far the reasons why and some aspects for setting up a network for collaboration as the direct equivalent of an community to the real-world, and how to choose a system for starting the development were given. What is important now is to argue about the way that this process should be managed and the restrictions that are imposed to it by the nature of the effort. The description of “how open the project can be”, is based on the Software Project Governance Framework that was presented in the second chapter.

The coordinating organisation should lead the process but at the same time allow for participation and involvement of users until a decision can be made, the reasons for suggesting this are based on the findings of the previous chapter. This would give a rating of two in the leadership dimension.

Upon every release quality assurance and thorough testing should be done to ensure the security and privacy of the systems and reduce the number of bugs in the released version. Privacy and security are key issues for the users, and bugs which might compromise the reliability of the systems can have serious safety implications. This would give a rating of one in the testing dimension as most of the testing should be done internally through a well organised process. Of course feedback from the users can serve as further testing and a way to increase the quality of the system though fixing those bugs, but prior testing and quality assurance are mandatory.

The coordinating organisation should have hired developers in order to drive the development forward and be able to impose some deadlines but it should also seek for the contributions of the community. A value of two in the contribution dimension should be adequate for reducing costs, meaning that anywhere between 50-80% of the code would be developed by hired developers. Since a good amount of developers should be hired, the core team would work on the same site with some remote

participants, and therefore a value of 2 will be given to the working practices dimension.

The rating is demonstrated in the figure below and it is quite close to what was described as a traditionally closed source project with open aspects.

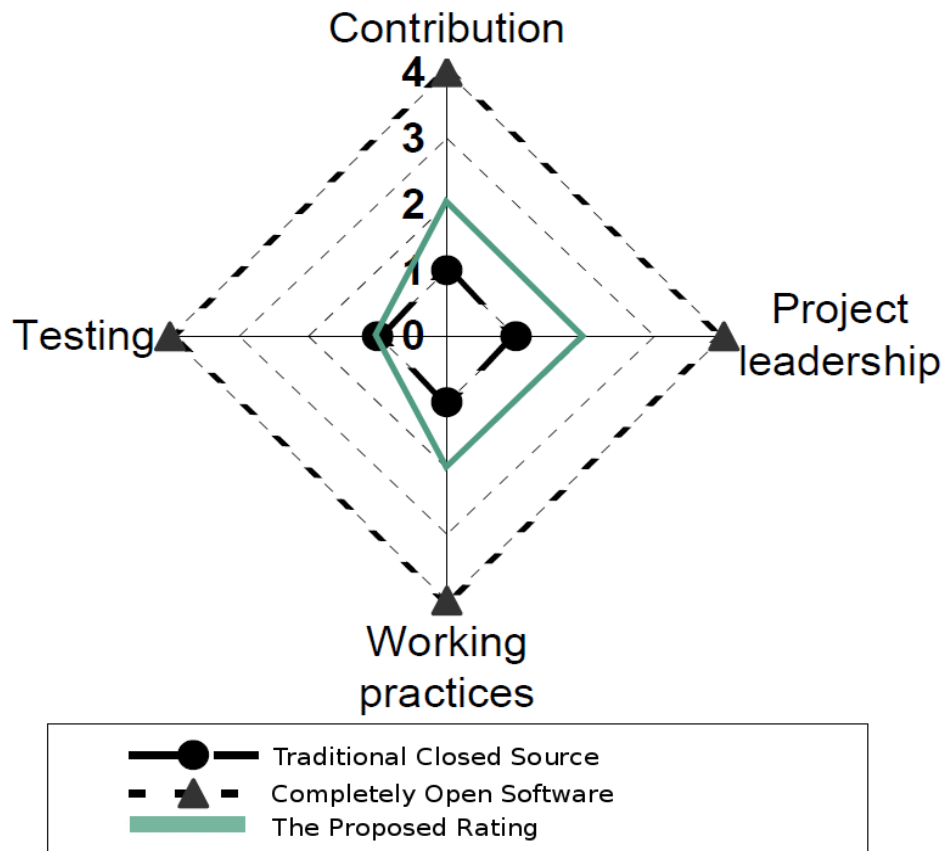


Figure 13: The Rating of The Process

#### 4.5 The Structure Of The Community

Setting up a community in the real-world should have taken place by now, the appropriate system or systems have been chosen to start the implementation and the ways of managing this process should be set. The collaborating network is a part of the OSS community. This section will argue why that would be the case and what possibilities does going online open.

The onion model and the project dynamics as they are described by three types of projects that were found by Nakakoji et al can be used to describe the structure of a community for this proposed project. We will start from the inner layers then move outwards.

The role of the leader should not be expected in this sort of project as a single individual handling this whole network does not seem like a good idea. The core team should be mostly comprised of hired developers but some type of promotion policies towards the core should be set to encourage involvement of active and peripheral developers. Nothing much can be said about peripheral and active developers due to the sporadic nature of the involvement of peripheral developers and their transformation to active developers. The readers of the project code can be members of the academia who are interested in reviewing the project for research purposes or teaching and learning. This would mean that students in Healthcare Informatics could use real systems and the input their users give to enhance their knowledge and prepare for the real world, while

researchers and teachers could expand their knowledge and affect current practice by providing peer review and valuable from their latest research.

The passive users will be the vast majority of the community. The special situation in the healthcare domain, calls for setting up a way of communication and bug reporting which might depart from the online discussion and mailing lists in OSS, something which is absolutely necessary for physicians who do not have enough time to begin with and active online participation should not be expected by them.

The development of the system should follow the dynamics of service oriented projects on the the basic functionality of the system and experiment with extensions and peripheral in order to provide innovations to otherwise stable services.

A software ecosystem can be set up on top of the system through the use of . This can be an application centric ecosystem [Bosch, 2009] with the system serving as a platform for innovation. This opens up business opportunities for companies which can develop commercial extensions. The commercial extensions and modules can be built on top of the project as well as systems which interface with the OSS EHR(s) to be built.

A wide participation of healthcare organisations, will result in a large market for applications built on top or around this system making them more attractive to potential customer organisations since interoperability can be guaranteed. User training, installation, maintenance, establishment of backup and disaster recovery processes and procedures, on-site training tailored to users' needs are good candidates for business models as well. This is a possible role for the software companies in the community.

#### **4.6 Conclusion**

Some aspects of an OSS development process approach were outlined in this chapter the complexity of every single issue makes it impossible to go in any more detail in the absence of a real world attempt of such an effort.

The involvement of academia allows practice and research to be closer offering benefits to both. The activity of the community and the information that can be shared on the experience of EHR adoption will create a large base for research, by providing information that is now missing.

A network of development and the combined effort of many organisations can lead to shared and reduced costs. Providing the systems for free would make them affordable to small organisations and individual practitioners allowing them to overcome the main barrier to adoption. On a national level the wide adoption of EHR systems which follow standards and therefore have a high degree of interoperability, would show to what extent the predictive research on savings for the healthcare systems is realistic and what are the limitations. The openness of the systems would also allow for vendor lock-ins to be avoided.

As most HIT leaders developed a system over time in a process of co-evolution, the same should be expected in other cases of EHR development as well, however it should happen in a more rapid fashion. An OSS process resembles this pattern in a large scale. The difference in scale and the lack of information on any effort of this sort makes it impossible to argue about other similarities and differences between the two cases or understand if this resemblance is qualitatively the same. It should be considered positive though that they share the similarity of evolutionary approach to development.

The community can enable communication and sharing experiences between the organisations allowing more experienced organisations to help those who are just starting and want to speed up their process. The feedback generated from the community can lead to improvements in the standards which can be widely used and tested in practice, improvements in the systems where one bug fix would improve the

quality of the systems in many institutions, and can provide insights to the suitability of the current type of systems to satisfy users' needs; and allow their evolution and emergence of different types of systems.

The communication with other HIS used in local settings can be accomplished through open interfaces in the short term, something that is already done with the closed source systems. In the long run this could be better for maintaining the systems and ensuring interoperability in the local setting, but during its initial stage it has no advantages over closed-source systems and might even pose a challenge. The connection with legacy systems is also a point which requires more attention.

The poor performance of the current systems, the increased transparency of development along with the number of potential benefits that were presented in this work might be a good reason for attempting a highly ambitious effort like this.

Benefits In	Description
Cost	Shared costs among organisations
	Avoiding vendor lock-in
	Higher adoption and interoperability result in savings for the healthcare system
Research	Allows academic involvement in implementation and review
	Creates a large base of information for research
Community	Sharing experiences
	Providing support
	Bug reporting and fixing

*Table 10: Possible Benefits*

## 5 Limitations And Future Directions

This work was an attempt to provide a way to use OSS for EHR systems in a way that goes beyond using software that is already developed by existing communities. The strength of this argument is limited by the lack of experience from the side of the author in the field of EHR and HIT. It might be the case that the depth of the problem cannot be properly conceptualised.

This work has a potential for expansion. Studying the EHR systems and providing a more detailed approach to all the aspects that were already analysed, finding possible errors in the current analysis, and a serious focus on the local setting would make many subjects clearer and strengthen the argument. The systems used together with EHR systems in the local setting and how this whole ecosystem of different applications is affected by the EHR could be analysed in more detail.

Other matters that can be analysed are the nature of the community, who directs it, who participates, what could the proper communication mechanisms be, business models and so on. Practically every issue touched on the previous chapter can be further elaborated and enriched.

A wider base of literature and case studies in OSS and finding a similar experience would create better insights for the use of an OSS development process. The existing communities developing OSS EHR systems and other HIS and their possible contribution or role in an effort like this could be examined. Given the international

nature of these communities they can provide diversity and resources to the development efforts.

Proving that the process of using commercially available systems trying to cover a large base of users and gain competitive advantage instead of developing the systems “in-house” or in a similar fashion would be a very strong argument in favour of an alternative approach and there are indications that this is the case. Of course that does not exclude all the for commercial activity in the domain of HIT systems or EHR systems as it was already explained.

Finally, an experiment of this sort would be the most valuable thing for expanding and validating this work or showing its limited value. At this point we could settle for a lot less, like expert validation which would still be extremely valuable and could provide a basis for future work and indicate if there is any valid point to continue in this direction.



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